

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>						Work Assignment Number 0-01				
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:				
Contract Number EP-W-16-017			Contract Period   06/13/2016   To   06/12/2017 Base <input checked="" type="checkbox"/> Option Period Number			Title of Work Assignment/SF Site Name Support for RRP				
Contractor BATTELLE MEMORIAL INSTITUTE					Specify Section and paragraph of Contract SOW					
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance  From   06/29/2016   To   06/12/2017				
Comments: Initiate Work Assignment. Contractor shall provide a work plan and cost estimate in accordance with the terms of the contract.										
<input type="checkbox"/> Superfund                      Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
SFO <input type="checkbox"/> Note: To report additional accounting and appropriations date use EPA Form 1900-69A. (Max 2)										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:		LOE:						
06/13/2016 To 06/12/2017				0						
This Action:				1,000						
Total:				1,000						
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:				Cost/Fee		LOE:				
Cumulative Approved:				Cost/Fee		LOE:				
Work Assignment Manager Name    Toiya Goodlow  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 202-566-2305 FAX Number:				
Project Officer Name    Cynthia Bowie  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 202-564-7726 FAX Number:				
Other Agency Official Name    Brian Nelson-Palmer  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 202-564-6190 FAX Number:				
Contracting Official Name    Sheila Dolan  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 202-564-4348 FAX Number:				

**Contract Number: EP-W-16-017**

**Work Assignment Number: 1-01**

**Change Number: 0**

**Title: Support for the Lead-Based Paint Program and Other National Program Chemicals**

## **I. Purpose and Background**

To provide technical support of the implementation of the Renovation, Repair and Painting Program (RRP) as well as all other aspects of the Lead-Based Paint Program. This is a continuation of work to extend the performance period that began under the previous work assignment, work assignment 0-01 of contract EP-W-16-017. No work shall be duplicated and no cost shall be added.

Title IV of the Residential Lead-Based Paint Poisoning Prevention Act requires EPA to undertake various actions to reduce the incidence of lead poisoning. These actions include technical studies to support rule making, outreach to the regulated community, outreach to the public and support of the regulatory functions.

Additionally, technical support is needed for other work in the National Program Chemicals Division (NPCD). NPCD is responsible existing chemicals that are ready for hazard management. Currently those chemicals include lead, mercury, formaldehyde, asbestos, dioxin and polychlorinated biphenyls (PCBs).

## **II. Scope of Work:**

### **Task 1 Storage of Records**

The Contractor shall arrange for storage facilities for RRP paper records. These are active records and must be available in the Washington, D.C. metropolitan area. The records must be stored in a secure area and be available for EPA personnel within 24 hours. When directed by the WAM, the Contractor shall arrange for pickup of additional records from within another location in the Washington, D.C. area. The Contractor shall maintain the existing filing methodology and file any new records accordingly.

### **Task 2 Cleaning Verification Cards**

The Contractor shall provide Cleaning Verification Cards that meet the quality control standards previously developed. The cards shall be shipped to the National Lead Information Center in Rochester, NY. It is anticipated that the cards will be produced in batches of 150,000. Assume one batch will be required.



### **Task 3 Support of the Outreach Efforts at Trade Shows**

The Contractor shall purchase exhibit space at trade shows and shall staff the EPA-provided booth. These services include shipping the EPA booth to the show and returning it to a location designated by the WAM. Also included in this task is paying for incidental fees such as drapes, delivery charges, etc.

### **Task 4 Technical Studies**

The Contractor shall produce studies on Lead-Based Paint issues. These studies are anticipated to be of short duration, typically less than 30 days. The exact nature of the study and due date will be contained in the technical direction. Anticipated topics are work practices on Public and Commercial Buildings and other rules in development. Also providing additional analyses on the Dust Study is anticipated.

### **Task 5 Revisions to Major Documents**

The Contractor shall provide draft documents of revisions to major documents such as “Protect Your Family” (PYF) and training manuals. It is anticipated that there will be several drafts of both the revised text and graphics. PYF is a joint publication of HUD and EPA and will need to be cleared by both agencies. The Contractor shall produce both an English and Spanish versions of the document. It may be necessary for the Contractor to convene one or more focus groups in both English and Spanish to determine the readability and understandability of the document. There may be other national program chemical documents to be revised, including special tasks for mercury and PCBs.

### **Task 6 Lead Outreach Support**

The Contractor shall provide support to a major outreach effort on outreach to the regulated community on the Renovation, Repair and Painting Rule and/or other regulations or topics related to lead. The Contractor shall provide assistance with identifying target audiences. This includes the purchase of mailing lists and associated services and purchase of advertising.

### **Task 7 National Program Chemicals Support**

The Contractor shall provide support to other national program chemicals including but not limited to mercury, formaldehyde, dioxin furans, asbestos and PCBs. The Contractor shall provide technical support for regulatory and non-regulatory activities involving risk reduction and hazard management of national program chemicals. Technical support includes but is not limited to technical studies and investigation supporting rule making, outreach to the regulated community, outreach to the public and support of regulatory and non-regulatory functions.

## **III. Deliverables:**

Tasks 1 to 3: A letter report providing statistics on the activity for the contract period shall be provided. This can be part of the monthly report.

Task 4. A draft and final report as detailed in the technical direction.

Task 5. CDs of the professional print files of the documents ready for printing.

Task 6. A letter report detailing the activities performed.

Task 7. A draft and final report as detailed in the technical direction.

**A work plan is required.**

**A QA/QC plan is required for Tasks 4 and 7. A QA/QC plan is not required for Tasks 1, 2, 3, 5 and 6.**

**CBI does not apply.**

This work assignment relates to Tasks II, III and IV of the current Statement of Work (SOW) of the contract.

**IV. Period of Performance:**

This work assignment will start on June 13, 2017 through June 12, 2018.

**V. Estimated Level of Effort: 845 professional hours**

**VI. EPA Contacts:**

Work Assignment Manager:

Toiya M. Goodlow  
US EPA National Program Chemicals Division  
Program Assessment and Outreach Branch (7404T)  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460  
Ph: 202-566-2305

Deputy Work Assignment Manager:

Julie Shannon  
US EPA National Program Chemicals Division  
Program Assessment and Outreach Branch (7404T)  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460  
Ph: 202-564-8834

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>						Work Assignment Number 1-02				
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:				
Contract Number EP-W-16-017			Contract Period   06/13/2016   To   06/12/2021 Base                      Option Period Number      1			Title of Work Assignment/SF Site Name				
Contractor Battelle Memorial Institute					Specify Section and paragraph of Contract SOW RRP Lead Outreach					
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval					Period of Performance  From   06/13/2017   To   06/12/2018					
Comments: Initiate work assignment for the new period of performance that begins on June 13, 2017. The contractor shall provide a workplan within 30 days of receipt of the work assignment.										
<input type="checkbox"/> Superfund                      Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
SFO <input type="checkbox"/> Note: To report additional accounting and appropriations date use EPA Form 1900-69A. (Max 2)										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:                      Cost/Fee:                      LOE: 06/13/2016   To   06/12/2021										
This Action:  										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:                      Cost/Fee                      LOE:										
Cumulative Approved:                      Cost/Fee                      LOE:										
Work Assignment Manager Name    Darlene Leonard  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 202-566-0516 FAX Number:			
Project Officer Name    Cynthia Bowie  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 202-564-7726 FAX Number:			
Other Agency Official Name  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: FAX Number:			
Contracting Official Name    Jody Gosnell  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 202-564-4353 FAX Number:			

**Contract Number: EP-W-16-017**

**Work Assignment Number: 1-02**

**Change Number: 0**

**Title: RRP Lead Outreach**

### **I. Purpose and Background**

This work assignment is a continuation of WA 0-02 under Contract EP-W-16-017. This Work Assignment continues and expands upon the work initiated in WA 0-02 under Contract EP-W-16-017 and provides technical support for the implementation of the Renovation, Repair and Painting Program as well as all other aspects of the Lead-Based Paint Program. No work shall be repeated that was previously completed in WA 0-02.

Title IV of the Residential Lead-Based Paint Poisoning Prevention Act requires EPA to undertake various actions to reduce the incidence of lead poisoning. Specifically Section 405 (a) says “ The Administrator, in cooperation with other appropriate Federal departments and agencies, shall conduct a comprehensive program to promote safe, effective, and affordable monitoring, detection and abatement of lead-based paint and other lead exposure hazards” Section 405 (d) says “the Administrator in conjunction with the Secretary of Health and Human Services...and in conjunction with the Secretary of Housing and Urban development, shall sponsor public education and outreach activities to increase public awareness...”

Throughout the year, EPA provides lead awareness and educational outreach to various audiences. In addition, EPA partners with the Centers for Disease Control and Prevention (CDC) and the Department of Housing and Urban Development (HUD) to collaborate on a theme and develop posters and flyers and other education and awareness tools and events specifically designed to observe National Lead Poisoning Prevention Week (NLPPW). EPA also promotes the Lead Week of Action, a lead awareness effort on an international scale.

### **II. Scope of Work**

#### **Task 5 General Lead Outreach**

The Contractor shall:

- Provide technical support for general lead outreach, including finalizing EPA pamphlets, poster, banners, flyers for web posting or printing, developing outreach presentations, support for developing, shipping and staffing conference exhibit booths and meetings, translation of existing EPA documents into additional languages, and outreach support involving Historically Black Colleges and Universities (HBCUs) as directed by the EPA WAM.

### **III. Deliverables:**

- Summary of Work  
The Contractor shall provide a letter report providing statistics on the activity for the contract period.
- Graphic Files and Support  
The Contractor shall provide graphic print files for documents (pamphlets, posters,

banners, flyers, social media postings, and other tools) and support for other outreach events and activities, as directed by the EPA WAM.

**A work plan is required.**

**A Quality Assurance Project Plan is not required since no data collection applies.**

**CBI does not apply.**

This work assignment relates to Tasks III and IV of the current Statement of Work (SOW) of the contract.

**IV. Period of Performance:**

This work assignment will start on the date of the Contracting Officer signature and extend through June 12, 2018.

**V. Estimated Level of Effort:** 80 professional hours

**VI. EPA Contacts:**

Work Assignment Manager:

Darlene Leonard  
US EPA National Program Chemicals Division  
Program Assessment and Outreach Branch (7404T)  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460  
Phone: 202-566-1859

Deputy Work Assignment Manager:

Julie Shannon  
US EPA National Program Chemicals Division  
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1200 Pennsylvania Avenue, NW  
Washington, DC 20460  
Phone: 202-564-8834

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>						Work Assignment Number 1-03				
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:				
Contract Number EP-W-16-017			Contract Period   06/13/2016   To   06/12/2021 Base                      Option Period Number      1			Title of Work Assignment/SF Site Name PCB/Disposal Cleanup				
Contractor Battelle Memorial Institute					Specify Section and paragraph of Contract SOW					
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance  From   06/13/2017   To   06/12/2018				
Comments: Initiate work assignment for the new period of performance that begins on June 13, 2017. The contractor shall provide a workplan within 30 days of receipt of the work assignment.										
<input type="checkbox"/> Superfund                      Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
Note: To report additional accounting and appropriations data use EPA Form 1900-69A.										
SFO <input type="checkbox"/> (Max 2)										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:                      Cost/Fee:                      LOE: 06/13/2016   To   06/12/2021										
This Action:										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:                      Cost/Fee                      LOE:										
Cumulative Approved:                      Cost/Fee                      LOE:										
Work Assignment Manager Name    Gail Hansen  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 703-308-0463 FAX Number:			
Project Officer Name    Cynthia Bowie  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 202-564-7726 FAX Number:			
Other Agency Official Name  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: FAX Number:			
Contracting Official Name    Jody Gosnell  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 202-564-4353 FAX Number:			

## Statement of Work

**Contract Number:** EP-W-16-017

**Work Assignment:** 1-03

**Amendment Number:** 0

**Title:** Technical Support for PCB Permits and Document Development

### **Background**

This work assignment is a follow-on to WA 03. There were not sufficient funds in the original budget to perform several tasks. This statement of work seeks to add funding *only* for Task 5: Finalization of “PCB Guidance” and Response to Comments.

### **Scope of Work**

A. The Contractor shall update the PCB Guidance that will help persons apply for approvals for alternative technologies under 40 CFR §761. The document will discuss requirements for approval applications, demonstration test plans, demonstration test reports, as well as describe the approval process and how to conduct a demonstration. This document will help persons apply for disposal and cleanup PCB approvals from the EPA.

### **Tasks**

#### **Task 1. Task Management**

The Contractor shall prepare and submit a work plan. Work under this task shall include participating in conference calls, meetings, preparing the monthly progress report and other task management.

#### **Task 5. Finalization of “PCB Guidance” and Response to Comments**

Contractor shall update and finalize a document entitled “*Guidelines for Approval Applications and Demonstration Test Plans for PCB Disposal by Non-Thermal Alternative Methods, Thermal Alternative Methods, and Incineration,*” also known as the “PCB Guidance.” Copies of the latest version of the guidance will be provided by the WAM to the contractor in Word.

Task will be divided into two phases:

**Phase 1** will be response to internal EPA comments. WAM will distribute the draft document to staff, management, general counsel, and regional personnel for comment. The Contractor shall incorporate comments from each set of commenters and prepare a draft document for public comment.

**Phase 2** will be response to external EPA comments. WAM will send out the draft guidance from Phase 1 to EPA stakeholders. Contractor shall collate the comments that come in from public comment and prepare a response to comment document. Contractor shall modify the PCB Guidance based on the response to comments and prepare a final version of the PCB Guidance which the WAM will distribute to persons desiring a PCB disposal approval.

This work assignment relates to Tasks III, IV, and V of the current contract statement of work.

**Deliverables**

<b>Deliverable</b>	<b>Schedule</b>
<b>Task 1:</b> Task Management	Within 30 days of issuance of Work Assignment, the Contractor shall submit a Work Plan for review and acceptance.
<b>Task 5:</b> Finalization of “PCB Guidance” and Response to Comments	<b>Phase 1:</b> Upon receipt of comments from staff, management, general counsel, and regional personnel, the Contractor shall incorporate them within 10 days. <b>Phase 2:</b> Upon receipt of public comments, contractor shall have 30 days to prepare the response to comment document and another 20 days to incorporate the comments into the final “PCB Guidance.”

**Period of Performance**

This work assignment will start on the date of the contracting officer’s signature and extend through June 13, 2018.

**Level of Effort**

The estimated level of effort for this requirement is: **200 hours**

**EPA Contacts**

**Work Assignment Manager**

Gail Hansen  
1200 Pennsylvania Ave NW  
Mail Code 5303P  
Washington, DC 20460  
Phone: (703) 308-0463

**Courier Service Address:**

One Potomac Yard  
2777 S. Crystal Drive  
Room S-6217  
Arlington, VA 22202



Work Assignment Form. (WebForms v1.0)

## **Amendment of Work**

**Contract Number:** EP-W-16-017

**Work Assignment:** 03-1

**Amendment Number:** 1

**Title:** Technical Support for PCB Permits and Document Development

### **Background**

This project adds *Task 7: PCB Database Entry* to the work assignment and moves part of the remaining funds and hours from *Task 5: Finalization of "PCB Guidance" and Response to Comments* to the new *Task 7*.

The reason for doing so is that EPA's management review of the PCB guidance is taking longer than expected and may not be completed before the work assignment ends. Therefore, EPA's management has decided to shift part of the remaining funds and hours into the new *Task 7*.

### **Scope of Work**

Several Regions have either an *Access* database or *Excel* spreadsheet containing their PCB notifications and PCB approvals data. Since EPA is moving to a national PCB database in *RCRAInfo*, there is a need to re-enter all the data from the Regional databases/spreadsheets into *RCRAInfo*. In particular, Region 1's database contains 757 entries and about 20 fields that are common to both databases. This work assignment amendment seeks to add a *Task 7* to the work assignment to have the Contractor perform the data entry from the Regional databases/spreadsheets into *RCRAInfo*, beginning with the Region 1 database.

### **Tasks**

#### **Task 1. Task Management**

The Contractor shall prepare and submit a work plan. Work under this task shall include participating in project update meetings/teleconferences, preparing the monthly progress reports and other task management.

#### **Task 7. PCB Database Entry - NEW**

The Contractor will enter as much of the PCB data from the Regional databases/spreadsheets into *RCRAInfo*, within the existing funding limits. Contractor will begin entering data from the Region 1 database, beginning with the most recent approvals/notification data. When more funding becomes available, Contractor will continue entering the remaining data from the Region 1 database as well as other Regional database/spreadsheets as they become available. Contractor will enter the data manually (i.e., typing) and perform a data entry quality assurance check (i.e., every field entered for every site will be double checked for correctness by a separate individual).

This work assignment relates to Tasks III, IV, and V of the current contract statement of work.

### **Deliverables**

<b>Deliverable</b>	<b>Schedule</b>
<b>Task 1:</b> Task Management	Within 30 days of issuance of Work Assignment Amendment, the Contractor shall submit a Work Plan for review and acceptance.
<b>Task 7:</b> PCB Database Entry	Upon receipt of databases from the Regions, the Contractor shall enter the data into RCRAInfo within 10 days.

### **Period of Performance**

This work assignment will start on the date of the contracting officer's signature and extend through June 13, 2018.

### **Level of Effort**

The estimated level of effort for this requirement is: **120 hours**. *NOTE: these hours DO NOT increase the level of funding but are part of the remaining 163.50 hours left in the work assignment per the December 2017 invoice.*

### **EPA Contacts**

#### **Work Assignment Manager**

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1200 Pennsylvania Ave NW  
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Washington, DC 20460  
Phone: (703) 308-0463

#### **Alternate Work Assignment Manager**

Jenny McLeod  
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Mail Code 5303P  
Washington, DC 20460  
Phone: (703) 308-8459

#### **Courier Service Address:**

One Potomac Yard  
2777 S. Crystal Drive  
Room S-6217  
Arlington, VA 22202

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>						Work Assignment Number 1-04				
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:				
Contract Number EP-W-16-017			Contract Period   06/13/2016   To   06/12/2021 Base                      Option Period Number    1			Title of Work Assignment/SF Site Name Formaldehyde				
Contractor Battelle Memorial Institute					Specify Section and paragraph of Contract SOW					
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance  From   06/13/2017   To   06/12/2018				
Comments: Initiate work assignment for the new period of performance that begins on June 13, 2017. The contractor shall provide a workplan within 30 days of receipt of the work assignment.										
<input type="checkbox"/> Superfund                      Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
SFO <input type="checkbox"/> Note: To report additional accounting and appropriations date use EPA Form 1900-69A. (Max 2)										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:		LOE:						
06/13/2016 To 06/12/2021				1						
This Action:				0						
Total:				1						
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:				Cost/Fee		LOE:				
Cumulative Approved:				Cost/Fee		LOE:				
Work Assignment Manager Name   Robert Courtnage  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 202-566-1081 FAX Number:				
Project Officer Name   Cynthia Bowie  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 202-564-7726 FAX Number:				
Other Agency Official Name  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: FAX Number:				
Contracting Official Name   Jody Gosnell  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 202-564-4353 FAX Number:				

**Contract Number: EP-W-16-017**

**Work Assignment Number: 1-04**

**Change Number: 0**

**Title: Support for Formaldehyde Compliance Guides and Other Outreach**

## **I. Purpose and Background**

To provide EPA technical support to develop guidance materials for the Formaldehyde Emission Standards for Composite Wood Products regulations. This project is a continuation of work assignment (WA) 0-04 under contract EP-W-16-017. This WA continues the work initiated in WA 0-04 under contract EP-W-16-017. No work shall be duplicated.

Title VI of the Toxic Substances Control Act (TSCA Title VI) establishes formaldehyde emissions for composite wood products and requires EPA to promulgate regulations to ensure compliance with these emission standards. EPA has promulgated regulations for TSCA Title VI which have requirements for manufacturers (including importers), fabricators and laminators of composite wood products. Other entities, such as retailers, wholesalers, and distributors are required to sell, supply, or offer for sale, only composite wood products that are compliant with the regulations. The regulations also establish a third-party certification program for composite wood products. The contractor shall translate and revise, as needed, small entity compliance guides, as required by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) and other rule compliance-related materials as directed by the work assignment manager (WAM). The contractor shall provide, as directed by the WAM, technical and graphical support for final rule implementation outreach including materials for the EPA Formaldehyde Resource Directory (website).

## **II. Scope of Work:**

### **Task 1: Develop a Work Plan**

The contractor shall prepare and submit a work plan in accordance with the contract requirements.

### **Task 2: Language Translations of Small Entity Compliance Guides**

For each of the final English language Compliance Guides including: 1) third-party certifiers and accreditation bodies, 2) panel producers, 3) importers, distributors and retailers, and 4) fabricators (including laminators), provide up to 3 language translations, as needed and as directed by the WAM. The final Compliance Guides must be in compliance with section 508 of the Rehabilitation Act.

### **Task 3: EPA Formaldehyde Resource Directory (website) Technical Support**

The contractor shall provide support, as directed by the WAM, for technical and graphical materials related to the Formaldehyde Emission Standards from Composite Wood Products final rule implementation and compliance including materials for the EPA Formaldehyde website.

### **III. Deliverables:**

**Task 1:** Work plan submitted within 30 working days of receipt of work assignment.

**Task 2:** The contractor shall provide the WAM written translations, in a language directed by the WAM, of the four English language Compliance Guides within 35 working days after being tasked by the WAM. The files shall be professional print-ready files and suitable for EPA web publication. The final translated Compliance Guides must be in compliance with section 508 of the Rehabilitation Act.

**Task 3:** As directed by the WAM provide graphics, displays, forms, etc., for print or for the EPA Formaldehyde website.

**A work plan is required.**

**A QA/QC plan is not required since no data collection applies.**

**CBI does not apply.**

This work assignment relates to Tasks III, and IV of the current Statement of Work (SOW) of the contract. The work assignment shall start upon the Contracting Officer's signature and extend to June 12, 2018.

**Estimated Level of Effort: 180 hours**

#### **WAM Contact Information:**

Robert Courtnage  
[courtnage.robert@epa.gov](mailto:courtnage.robert@epa.gov)  
202-566-1081

#### **Deputy WAM Contact Information:**

Todd Coleman  
[Coleman.todd@epa.gov](mailto:Coleman.todd@epa.gov)  
202-564-1208

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>						Work Assignment Number 1-04				
						<input type="checkbox"/> Other <input checked="" type="checkbox"/> Amendment Number: 000001				
Contract Number EP-W-16-017			Contract Period 06/13/2017 To 06/12/2018			Title of Work Assignment/SF Site Name				
			Base                      Option Period Number    1			Formaldehyde				
Contractor BATTELLE MEMORIAL INSTITUTE					Specify Section and paragraph of Contract SOW					
Purpose: <input type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input checked="" type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval					Period of Performance  From 06/13/2017 To 06/12/2018					
Comments: The purpose of this Amendment is to add 70 hours to the LOE. The Contractor submit a work plan within 30 days of receipt of the work assignment amendment.										
<input type="checkbox"/> Superfund                      Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
SFO <input type="checkbox"/> (Max 2)                      Note: To report additional accounting and appropriations date use EPA Form 1900-69A.										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
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5										
Authorized Work Assignment Ceiling										
Contract Period:                      Cost/Fee:                      LOE: 06/13/2017 To 06/12/2018										
This Action:  										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:                      Cost/Fee                      LOE:										
Cumulative Approved:                      Cost/Fee                      LOE:										
Work Assignment Manager Name    Robert Courtnage  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 202-566-1081 FAX Number:			
Project Officer Name    Tyrone Thomas  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 202-564-3121 FAX Number:			
Other Agency Official Name  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: FAX Number:			
Contracting Official Name    Jody Gosnell  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 202-564-4353 FAX Number:			

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>						Work Assignment Number 1-05				
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:				
Contract Number EP-W-16-017			Contract Period   06/13/2016   To   06/12/2018 Base                      Option Period Number    1			Title of Work Assignment/SF Site Name Statistical Supp Clean Water				
Contractor BATTELLE MEMORIAL INSTITUTE					Specify Section and paragraph of Contract SOW					
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance  From   06/13/2017   To   06/12/2018				
Comments: Initiate work assignment for the new period of performance that begins on June 13, 2017. The contractor shall provide a workplan within 30 days of receipt of the work assignment.										
<input type="checkbox"/> Superfund                      Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
SFO <input type="checkbox"/> Note: To report additional accounting and appropriations date use EPA Form 1900-69A. (Max 2)										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:		LOE:						
06/13/2016 To 06/12/2018				0						
This Action:				1						
Total:				1						
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:				Cost/Fee		LOE:				
Cumulative Approved:				Cost/Fee		LOE:				
Work Assignment Manager Name    Brian Schnitker  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 202-566-0838 FAX Number:				
Project Officer Name    Cynthia Bowie  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 202-564-7726 FAX Number:				
Other Agency Official Name  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: FAX Number:				
Contracting Official Name    Jody Gosnell  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 202-564-4353 FAX Number:				



**Contract No. EP-W-16-017**  
**Work Assignment 1-05**

**TITLE: Statistical Support for Clean Water Act**

**This new work assignment relates to Task I Collection of Data, Task II Data Analysis, and to a lesser extent, Task III Technical Program Support - General Support, of the current Statement of Work (SOW) of the contract.** In particular, the work assignment will provide support for activities authorized by the Clean Water Act. The contractor shall provide support in areas including statistical analysis of laboratory data, statistical review and comment, and statistical documentation. A work plan is required (see Task 1).

This Work Assignment will provide follow-on statistical support for the NY/NJ Harbor and Super Storm Sandy Study (Task 10 in WA 4-4 under Contract EP-W-09-024) and monitoring support (Task 13 in WA 4-4). The WA also will provide statistical support for designing a survey of POTWs (i.e., a new project). The WA's tasks do not duplicate statistical support previously tasked elsewhere. EPA will not provide any data/information that are Confidential Business Information (CBI) for use in the work assignment.

## **I. BACKGROUND**

### *A. NY/NJ Harbor Statistical Analyses (Task 3)*

EPA plans for the work to be completed by **August 30, 2017**. This deadline applies to Task 3 only, not the entire work assignment.

For its assessment of post-SSS conditions in the summer of 2013, EPA-Region 2 collected samples from sites selected from the previous 2008 REMAP probability-based sampling design. Starting on October 28, 2012, Super Storm Sandy (SSS) arrived offshore of NY and NJ with hurricane force winds, heavy rainfall, and a tidal surge that damaged or destroyed approximately 500,000 homes and businesses, caused breaches in the barrier islands, and inundated Superfund sites and wastewater treatment facilities. Resultant flooding, as well as sustained power outages, released and/or redistributed contaminants. The NY/NJ Harbor complex (Upper Harbor, Lower Harbor, Newark Bay and Jamaica Bay), as well as Barnegat Bay in NJ, and freshwater tributaries along the coast were the USEPA-Region 2 water resources that were particularly impacted.

Using EPA's consolidated database, the contractor shall use the data from the 1993/4, 1998, 2003, 2008 and 2013 Harbor samples and the freshwater biological sampling results to statistically compare and assess pre- to post-SSS sediment conditions and any trends that may be present. None of the data are CBI.

It should be noted that much of this task has been completed and EPA does not expect a significant amount of work to be performed on this task. Time should be allotted, however, to address any issues or refinements of the final report and working with EPA to complete the upload of the database to STORET.

The study objectives are as follows:

1. Objective 1 (NY/NJ Harbor sediment survey)

Determine whether there are statistical differences in the areal extent and levels of sediment contaminants, sediment toxicity, and condition of benthic macroinvertebrate assemblages in the NY/NJ Harbor between 2008 and 2013.

2. Objective 2 (Intensive survey of 4 WWTP receiving waters)

Conduct bacteriological water and sediment contaminant sampling in the waterbodies that receive the discharge from the following wastewater treatment plants (WWTPs) or pump stations in NY and NJ. The current data from these WWTPs will be compared to standards and previously collected data.

- a. Bay Park WWTP
- b. Middlesex County Utilities Authority, NJ pump stations (2)
- c. Passaic Valley Sewerage Commission
- d. Yonkers WWTP

3. Objective 3 (Freshwater biological sampling)

Determine whether there are statistical differences in the condition of benthic macroinvertebrate communities in the freshwater portions of NJ Water Management Areas (WMAs) 4, 7, 9, and 12 by comparing current results with historical data.

*B. Statistical Design of POTW Study (Task 4)*

Because there is no comprehensive national baseline data set for POTW nutrient removal performance, EPA is considering a survey that would include multi-phase sampling with a screener, detailed questionnaire, and monitoring of POTWs and possibly nearby ambient waters. From EPA's bio-solids survey, EPA has a sampling frame, for another project under Contract EP-W-09-024, that need to be statistically evaluated and possibly modified for use in the POTW Study. EPA also requires support in developing a sample design and documentation for the survey. None of the data will be CBI.

*C. Statistical Analysis of Monitoring Data (Task 5)*

Throughout the year (i.e., period of performance), EPA occasionally needs statistical support on a quick turn-around basis for initiatives under the Clean Water Act. Such projects tend to focus on a relatively small issue that can be addressed with relatively low effort within 2-4 weeks. EPA

will identify the datasets and analysis objectives related to monitoring data. None of the data will be CBI.

### **Task 1: Work Plan and Cost Estimate**

The contractor will provide a work plan that describes the support that will be provided; identifies deliverables; and identifies potential problems that may arise in completing this work assignment on schedule and within budget. The work plan shall individually identify the estimated LOE and costs separately for each of the tasks on the WA.

The contractor shall provide overall work assignment management and interface with the EPA WACOR.

<b>TASK 1 – DELIVERABLES</b>	
<b>Deliverable</b>	<b>Due Date</b>
Work plan	• Due 30 calendar days following receipt of Work Assignment.
Interface with EPA WACOR	• As needed

### **Task 2: Quality Assurance**

Quality Assurance Project Plans are required under the Agency’s Quality Assurance Policy CIO-2105, formerly EPA Order 5360.1A2 and implementing guidance CIO-2105-P-01-0. All projects that involve the generation, collection, analysis and use of environmental data must have an approved QAPP prior to the commencement of the work.

#### *QA Project Plan Requirements*

EPA policy requires that an *approved* Quality Assurance Project Plan (QAPP) be in place before any work begins that involves the collection, generation, evaluation, analysis or use of environmental data. In addition to abiding by its own Quality Management Plan, the contractor shall adhere to the following requirements for:

- Task 3 (NY/NJ Harbor support), the contractor shall adhere to “Quality Assurance Project Plan: Post-Super Storm Sandy (SSS) Water Quality Monitoring in Coastal New Jersey and New York (“SSS QAPP”).” Unless already provided to EPA, the contractor shall provide the EPA WACOR with copies of the QAPP certification page signed by the contractor’s QAO, the contract’s project manager, the work assignment leader, and any other person providing substantial support to the task.
- Task 4 (POTW Study), the contractor shall adhere to a project-level QAPP or, upon receiving technical direction, shall develop a QAPP for the statistical activities described in Task 5. If the EPA WACOR provides technical direction that revisions are determined to be necessary, the contractor shall submit a revised QAPP, including the revision summary, within 10 to 15 work days, depending on the complexity of the changes. When preparing this revised version, the contractor shall ensure that it is written in an active voice and shall include a version history page that summarizes changes made. The contractor shall also provide the revised QAPP in track changes and compare document. The contractor also shall provide EPA with copies of any modified SOPs or checklists.

The EPA WACOR shall formally accept these for project records by providing a signature page that includes the EPA WACOR's and EPA QAO's signatures. EPA shall review the revised QAPP and provide the contractor with written approval or comments. The contractor shall provide a final revised QAPP responding to any EPA comments within 10-15 work days of receiving EPA's comments.

- Task 5 (Quick Response), the contractor shall adhere to the contractor's QMP. Because the contractor will only provide limited support that will be reviewed by EPA statistician(s), EPA has determined that QAPPs are not necessary for these tasks.

#### *Additional QA Documentation Required*

In addition to the QAPP requirements described above and already required by Task 2, all major deliverables (e.g., Technical Support Documents, Study Reports, Study Plans, etc.) must include a discussion of the QA/QC activities that were or shall be performed to support the deliverable. For example, a Technical Support Document or Study Report must include a clear discussion of the quality management strategies that were employed to control and document the quality of data generated and used.

For any QAPP developed under this work assignment, the contractor shall verify that the QAPPs:

- Addresses all activities identified in this PWS that involve the **generation** (including field studies, laboratory studies, and modeling output), **collection** (including surveys, literature searches, and third party data), **evaluation** (including data inspection, review, assessment, and validation), **analysis** (including statistical, engineering, and economic analysis and testing, evaluation, and validation of methods and models) **and use of data** to support EPA decisions, regulations, policy, publications or tools (including effluent guidelines, methods, criteria, standards, environmental assessments, and models, tools, or reports disseminated by EPA to assist other organizations in implementing environmental programs). Examples of data include, but are not limited to, wastewater sample analysis results, flow measurements or data, facility questionnaire data, economic data, field sample data and laboratory analyses results, use of models, secondary data (including sources and the acceptance criteria), any software and database management requirements and any other relevant work that might affect the quality of the data. Note that QAPPs are also required for the development or revision of models and software that support the generation, collection, evaluation, analysis or use of data. For example, when existing models are used as a tool to generate or evaluate data, the project QAPP must describe the model, how it shall be used, and how the model output shall be evaluated to ensure it meets the overall quality objectives for the project. However, development or revision of new models also must be supported by a QAPP that describes the objectives for the model, the quality criteria that shall be applied to the model, and the procedures for evaluating whether the model meets those criteria.
- Provides enough detail to clearly describe objectives of the project supported by the work assignment; the type of data to be collected, generated, or used under this work assignment to support the project objectives; the quality objectives needed to ensure that these shall support the project objectives; and the quality assurance and quality control activities to be performed to ensure that any results obtained are documented and are of the type, quality, transparency, and reproducibility needed.

- Includes specific performance criteria and measures that shall be used to verify that data generated, collected or used in this work assignment meet those criteria. If a database or other electronic tool (e.g., model, spreadsheet, etc.) shall be created for the project, the QAPP must describe how the database or electronic tool shall be documented (e.g., data element dictionary, user manual, SOP, or other means appropriate for the project), the controls to ensure accurate data entry (when data from another source are manually entered into the database), data transfer (when data are transferred from one electronic medium to another), or data merging (when data from multiple databases or electronic media are merged into a single database).
- Explicitly references tools, such as SOPs, checklists, and guidelines that the contractor shall use in the project to document data quality. The QAPP must include the tools as attachments for EPA's review and acceptance.
- Addresses the following general questions:
  - What is the objective/goal of this effort?
  - What are the roles and responsibilities of staff who shall support this project, and how to they relate to the specific key steps?
  - What training and competency requirements are necessary for key personnel that shall support the project?
  - If models shall be used to support the project, what are these models, why have they been selected, and how shall they be validated, documented, and used?
  - What are the SOPs, tools and checklists that shall be used?
- **Under no circumstances shall work that involves the generation, collection, evaluation, analysis, or use of environmental data be performed without an approved QAPP (or addendum) in place 50 work days after submission of the contractor's work plan.**
- Under no circumstances shall field sampling or laboratory analysis activities be conducted prior to receipt of an approved work plan.
- Any non-sampling/non-analytical work that involves the generation, collection, evaluation, analysis, or use of environmental data that is initiated prior to approval of the contractor's QAPP must be performed in accordance with the approved QAPP. (The QAPP requirements must be applied retroactively to this period that lasts no more than 50 work days from submission of the contractor's work plan).

#### *Data Quality Act/Information Quality Guidelines Requirements*

The Data Quality Act (also known as the Information Quality Act) requires EPA to ensure that influential information disseminated by the Agency is sufficiently transparent in terms of data and methods of analysis that the information is capable of being substantially reproduced. To support compliance with these data transparency/data reproducibility requirements, EPA plans to include QAPPs as part of any rulemaking record documentation to be made available to the public.

Information contained in the approved QAPP must be transparent and reproducible and meet the requirements of the Data Quality Act for influential information. EPA's *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity, of Information Disseminated by the Environmental Protection Agency* (EPA/260R-02-008, October 2002), referred to as "EPA's Information Quality Guidelines," describe EPA procedures for meeting Data Quality Act

requirements. Section 6.3 of EPA’s Information Quality Guidelines indicate that “especially rigorous robustness checks” should be applied in circumstances where quality-related information cannot be disclosed due to confidentiality issues. Where applicable, the contractors should indicate which results were obtained using the tools (SOPs, checklists, and guidelines) that the contractor designates as confidential so that the EPA WACOR can easily identify the areas that shall require rigorous robustness checks and document that those checks have been performed.

*Additional QA Documentation Required*

In addition to the QAPP requirements described above, all major deliverables (e.g., Technical Support Documents, Study Reports, Study Plans, etc.) produced by the contractor under this work assignment must include a discussion of the QA/QC activities that were or shall be performed to support the deliverable. For example, a Technical Support Document or Study Report must include a clear discussion of the quality management strategies that were employed to control and document the quality of data generated and used.

The contractor also shall provide EPA with monthly reports of QA activities performed during implementation of this work assignment. For each of Tasks 3 to 7, these monthly QA reports shall identify QA activities performed to support implementation of this work assignment, problems encountered, deviations from the QAPP, and corrective actions taken. If desired, the contractor may include this as a part of the contract-required monthly financial/technical progress report. In addition, the contractor shall provide timely notification to the EPA WACOR of any QA problems that may affect the conduct of the tasks, with recommendations for corrective actions.

<b>TASK 2 – DELIVERABLES</b>	
<b>Deliverable</b>	<b>Due Date</b>
Signed QAPP certification pages for SSS (Task 3) and, if provided, project-level POTW Study (Task 4)	Any new assigned personnel to the projects, who will provide substantial support, have 5 work days from start of the assignment.
QAPP for statistical support for POTW Study	The first draft is due 15 work days after receiving technical direction. Revisions and final version are due in 1-10 work days, depending on complexity, as specified in technical direction.
QA/QC section in all major deliverables	Per schedule for major deliverables
QA/QC progress reports	One per month per task (may be included in progress report)
Email identifying QA/QC issues and recommended action	Timely notification when EPA WACOR input is required for proceeding on task.

**Task 3: Statistical Analysis of Sediment Data NY/NJ Harbor System**

**The contractor shall not proceed with this task until the EPA WACOR issues technical direction.** The contractor shall provide statistical analysis support for the Region 2 NY/NJ Harbor Project Information for Sediment Quality of the NY/NJ Harbor System.

The contractor shall

- a. Continue to compile and statistically evaluate NY/NJ data from Task 10 of Contract EP-W-09-024. The contractor shall:
  - i. Provide interim draft outputs from ongoing statistical analyses for EPA review and input.
  - ii. Provide interim databases for EPA use.
  - iii. Provide a draft report which provides and describes the data, compares data between years, and presents the statistical results with their interpretation. At a minimum, the memorandum shall describe the data, methodology, assumptions, results, quality assurance, conclusions, and recommendations for additional research. The contractor shall provide sufficient details and clarity in the report so that the work will be transparent and reproducible. The contractor shall revise the report to incorporate the EPA WACOR's written comments.
  - iv. Provide a final version that incorporates high quality graphics and stock photographs that are:
    - Formatted in JPEG or TIFF format (300 dots per inch or higher); and
    - Accompanied with captions.
  - v. Participate in weekly 90-minute teleconferences to discuss the progress and results. The contractor must include its statistical expert(s).
  - vi. Provide supporting materials which shall include final versions of data listings, spreadsheets, computer programs, and, if appropriate, flowcharts showing relationships between them.
  - vii. Upload the final database into WQX.

**Track** and report the technical progress, LOE, and costs separate from the other tasks on this work assignment.

<b>Task 3 – DELIVERABLES</b>		
<b>Subtask</b>	<b>Deliverable</b>	<b>Due Date</b>
a. Implementation	Interim draft analyses	Two days prior to teleconference for which EPA and the contractor will discuss the outputs.
	Draft databases	5 work days after receiving technical direction.
	Report	The first draft is due 15 work days after receiving technical direction to start the task. Revisions and final version are due in 1-10 work days, depending on complexity, as specified in technical direction.
	Teleconference	The EPA WACOR will schedule the date and time upon consultation with the contractor, and cancel as appropriate.
	Supporting documentation	5 work days after receiving technical direction.



Task 3 – DELIVERABLES		
Subtask	Deliverable	Due Date
	WQX upload	5 work days prior to end of period of performance or 10 work days after EPA accepts the final report
b. Tracking	Technical progress, LOE, and cost reports	Monthly with progress report.

#### **Task 4. POTW Study**

**The contractor shall not proceed with this task and each subtask until the WACOR issues technical direction.** The contractor shall:

- a. Evaluate the sample frame provided by the WACOR, which includes the Targeted National Sewage Sludge Survey (TNSSS) bio-solids sample frame. (EPA will provide documentation and databases from the bio-solids sample frame used in Contract EP-C-05-030 and WA 4-4 in Contract EP-W-09-024 and the added information that compiled under a separate effort.) Provide a written assessment of the sample frame and the ease of using it to develop a sampling plan. Identify any deficiencies and recommend actions to remedy them.
- b. Design statistical sampling plans for the POTW study. The contractor shall design these plans to achieve EPA's goals and objectives for statistical inferences about the populations. The contractor shall estimate and technically evaluate the precision associated with the sampling plans, the subpopulations in the strata, and post-stratification. The contractor also shall include recommendations in the sampling plans for identifying and handling anomalies. The contractor shall estimate the burden and costs for the respondents and EPA of implementing the sampling plans. The contractor shall attend up to four 1-day meetings to discuss study objectives at EPA HQ and participate in weekly teleconferences discussing objectives and progress.
- c. Provide statistical review, comment, and analysis of survey designs (e.g., from industry) provided to the contractor by EPA. The contractor shall technically evaluate whether the survey designs will achieve EPA's objectives and allow for statistical inferences from the results.
- d. Provide review and comment on drafts of survey instruments, related letters, and supplemental information to ensure that EPA is collecting the necessary information to execute the sampling plan. The contractor shall evaluate each survey instrument for clarity, content, design, format, structure, and consistency with EPA's objectives.
- e. Draft portions of statistical documentation of ICR packages that shall be consistent with EPA objectives, the Paperwork Reduction Act, Executive Order 12866, and Office of Management and Budget requirements.

**Track** and report the technical progress, LOE, and costs separate from the other tasks on this work assignment.

Task 4 – DELIVERABLES		
Subtask	Deliverable	Due Date
a	Memo with sample frame recommendations	5 work days after receiving technical direction. Revisions within 2-15 work days depending on complexity and urgency.



Task 4 – DELIVERABLES		
Subtask	Deliverable	Due Date
b	Sampling plans	15 work days after receiving technical direction. Revisions within 2-15 work days depending on complexity and urgency, per technical direction. EPA WACOR will schedule dates and times upon consultation with the contractor, and cancel as appropriate.
	Meetings	EPA WACOR will schedule dates and times upon consultation with the contractor.
	Teleconferences	EPA WACOR will schedule dates and times upon consultation with the contractor, and cancel as appropriate.
c and d	Memo with reviews	5-10 work days depending on complexity and urgency, per technical direction.
e	Draft ICR sections and supporting documents	5-10 work days depending on complexity and urgency, per technical direction.
f	Technical progress, LOE, and cost reports	Monthly with progress report.

#### **Task 5 Quick Response Statistical Analyses of Monitoring Data**

**The contractor shall not proceed with this task until the EPA WACOR issues technical direction.** The contractor shall determine and apply appropriate statistical procedures and methodologies in analyzing and interpreting monitoring data. The types of methodologies shall include, but not be limited to: nonparametric statistics, multivariate analysis, regression analysis, maximum likelihood estimation, analysis of variance, time series, categorical data analysis, survey statistics, inferential statistics, spatial analysis, survival analysis, statistical meta-analysis, and graphical analysis. The contractor shall clearly specify the methods, procedures, assumptions, relevant citations, data sources, and data that support the results and any recommendations. The contractor also shall document the reasons for selecting particular procedures, methodologies, and assumptions; and alternative methods, procedures, and assumptions that the contractor considered in the statistical analysis. EPA will review all outputs and provide agency input/changes. The contractor shall incorporate the changes specified by EPA. The contractor shall track and report the technical progress, LOE, and costs separate from the other tasks on this work assignment.

Task 5 – DELIVERABLES	
Deliverable	Due Date
Statistical Analysis (memo)	Within 1-10 work days, depending on complexity, as specified in technical direction. Revisions within 1-5 work days, depending on complexity, as specified in technical direction.
Programs and input data files	Within 5 work days after receiving technical direction.

Task 5 – DELIVERABLES	
Deliverable	Due Date
Technical progress, LOE, and cost reports	Monthly with progress report.

**II. TRAVEL:** The contractor shall attend up to three 1-day meetings in Washington, DC in support of Task 4.

**III. PERIOD OF PERFORMANCE:** This work assignment will start on the date of the contracting officer's signature and extend through the following 365 days.

**IV. ESTIMATED LEVEL OF EFFORT:** 400 hours

**V. EPA CONTACTS:**

**Work Assignment Contracting Officer Representative (WACOR):**

Brian Schnitker  
Phone: 202-566-0838  
e-mail: [schnitker.brian@epa.gov](mailto:schnitker.brian@epa.gov)

**Alternate WACOR:**

Paul Shriner  
Phone: 202.566.1076  
e-mail: [shriner.paul@epa.gov](mailto:shriner.paul@epa.gov)

**USPS Address (for WACOR):**

U.S. EPA (4503T)  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460

**Overnight Courier Address (for WACOR):**

U.S. EPA  
7313C EPA West  
1301 Constitution Avenue, NW  
Washington, DC 20004

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>						Work Assignment Number 1-06				
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:				
Contract Number EP-W-16-017			Contract Period   06/13/2016   To   06/12/2018 Base                      Option Period Number      1			Title of Work Assignment/SF Site Name Chemical Hazard and Exposure				
Contractor BATTELLE MEMORIAL INSTITUTE					Specify Section and paragraph of Contract SOW					
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance  From   06/13/2017   To   06/12/2018				
Comments: Initiate work assignment for the new period of performance that begins on June 13, 2017. The contractor shall provide a workplan within 30 days of receipt of the work assignment.										
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Note: To report additional accounting and appropriations data use EPA Form 1900-69A.										
SFO <input type="checkbox"/> (Max 2)										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
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Authorized Work Assignment Ceiling										
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This Action:										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:                      Cost/Fee                      LOE:										
Cumulative Approved:                      Cost/Fee                      LOE:										
Work Assignment Manager Name    Jeffrey Taylor  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 202-564-8828 FAX Number:			
Project Officer Name    Cynthia Bowie  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 202-564-7726 FAX Number:			
Other Agency Official Name  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: FAX Number:			
Contracting Official Name    Jody Gosnell  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 202-564-4353 FAX Number:			

**Contract Number: EP-W-16-017**

**Work Assignment Number: 1-06**

**Title: Chemical Hazard and Exposure Evaluation and Risk Management**

**Purpose:**

This work assignment continues and expands upon the work initiated under Work Assignment 0-06 of Contract EP-W-16-017. No work performed under previous work assignments will be duplicated under this work assignment.

**I. Background:**

This work assignment, entitled *Chemical Hazard and Exposure Evaluation and Risk Management*, was developed to provide EPA with support in analyzing existing chemicals and pursuing work for those chemicals that have the highest risk.

EPA's Existing Chemicals Program addresses pollution prevention, risk assessment, hazard and exposure assessment and characterization, and risk management for chemical substances in commercial use. For the chemicals that EPA identifies as high risk, EPA will choose from among many actions that it is authorized to take under the current Toxic Substances Control Act (TSCA). The Agency may pursue such regulatory actions as: restricting chemical use through banning its manufacture/import, issuing Significant New Use Rules that require manufacturers/importers to alert EPA of any new uses, and publishing test rules that require the chemical industry to supply EPA with additional data. Among other options, the Agency will also analyze safer substitute chemicals and consider voluntary phase-outs from the chemical manufacturers.

**II. Scope of Work:**

**Subtask 1. Work Plan and Task Management**

The contractor shall prepare and submit a work plan in accordance with the attached statement of work. Work under this subtask will include participating in conference calls, preparing monthly progress reports, and other task management.

**Subtask 2. Rulemaking Support**

The contractor shall help EPA develop rules, such as TSCA section 4 test rules that secure additional chemical data, section 5 Significant New Use Rules (SNURs) that deal with new uses, and section 6 rules that restrict chemicals. Work may include analyzing literature sources, or managing information that was developed by EPA or outside entities (e.g., other agencies, states, countries, NGOs, foundations, universities, and companies). The contractor may help collect, organize, and summarize public comments that are submitted by entities such as public interest groups, industry, academia, and others to EPA rulemaking dockets.

**Subtask 3. Meeting & Workshop Support**

The contractor shall assist EPA with meeting support by taking notes during meetings, such as at weekly one-hour division director-level meetings, at periodic and variable-length EPA rulemaking meetings, and/or at rulemaking consultation meetings that deal with tribal, small business, and state issues. The

contractor will produce the meeting/workshop notes and also incorporate any edits to those notes provided by EPA. Additional support may be conducted for expert meeting workshops, and may require the contractor to solicit attendees, organize logistics, facilitate the workshop, and summarize the discussions that take place at the workshop.

#### **Subtask 4. Chemical Prioritization & Work Plan Chemicals**

The contractor may assist EPA with identifying priority chemicals for risk management analysis. Work could include securing lists of chemicals that are being analyzed by: other countries, states within the United States, and EPA or other Federal agencies. The contractor may present information related to hazard, exposure, risk, and different environmental mediums such as air, water, and soil. The contractor may help EPA identify and take follow-up action on Work Plan chemicals that generally have the greatest risk concerns.

#### **Subtask 5. Chemical Data Reporting (CDR)**

The contractor may assist EPA with managing chemical data under its CDR. Support can include working with the 2016 CDR and 2012 CDR, helping with Internet and outreach materials, and producing statistics and chemical lists that relate to production volume, companies, industrial processing and use, and consumer and commercial use, among other information.

#### **Subtask 6. High Production Volume (HPV) Chemical Management**

The contractor shall continue to maintain HPV Challenge Program records, and conduct queries on HPV Challenge Program data if needed. The contractor may also perform work with other HPV chemicals.

#### **Subtask 7. Miscellaneous Hazard, Exposure, and Risk Analyses**

The contractor shall conduct analyses regarding other miscellaneous hazard, exposure, and risk management projects as the need arises.

### **III. Deliverables:**

Subtask 1.	The contractor shall prepare and submit the work plan in accordance with contract requirements.	
Subtask 2.	Rulemaking Support	At WAM's Request.
Subtask 3.	Meeting & Workshop Support	At WAM's Request.
Subtask 4.	Chemical Prioritization & Work Plan Chemicals	At WAM's Request.
Subtask 5.	Chemical Data Reporting (CDR)	At WAM's Request.
Subtask 6.	HPV Chemical Management	At WAM's Request.
Subtask 7.	Miscellaneous Hazard, Exposure, & Risk Analyses	At WAM's Request.

- A QA plan is required.
- A work plan is required.
- CBI does apply.

- The work assignment relates to: Task II, Subtask 1; Task III, Subtasks 1, 8, and 13; and Task IV, Subtask 3 of the contract SOW.

**IV. Period of Performance:**

This Work Assignment will begin on the date of the Contracting Officer's signature and extends through June 12, 2018.

**V. Estimated Level of Effort Hours:** 940

**VI. EPA Contacts:**

**Primary Contracting Officer Representative**

Jeffrey Taylor  
WJC East Building, Rm 4134-E, MC 7405M  
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**Alternate Contracting Officer Representative**

Tyler Lloyd  
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[lloyd.tyler@epa.gov](mailto:lloyd.tyler@epa.gov)

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>						Work Assignment Number 1-06				
						<input type="checkbox"/> Other <input checked="" type="checkbox"/> Amendment Number: 000001				
Contract Number EP-W-16-017			Contract Period   06/13/2017   To   06/12/2018 Base                      Option Period Number      1			Title of Work Assignment/SF Site Name				
Contractor BATTELLE MEMORIAL INSTITUTE					Specify Section and paragraph of Contract SOW Chemical Hazard and Exposure Evaluation and Risk					
Purpose: <input type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input checked="" type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval					Period of Performance  From   06/13/2017   To   06/12/2018					
Comments: Amended to update statement of work for Battelle WA 1-06, by increasing LOE to 1940. Contractor shall provide workplan 30 days after receipt of work assignment.										
<input type="checkbox"/> Superfund                      Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
SFO <input type="checkbox"/> Note: To report additional accounting and appropriations date use EPA Form 1900-69A. (Max 2)										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:			LOE:					
06/13/2017   To   06/12/2018										
This Action:										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:				Cost/Fee			LOE:			
Cumulative Approved:				Cost/Fee			LOE:			
Work Assignment Manager Name   Jeffrey Taylor							Branch/Mail Code:			
_____ (Signature)                      (Date)							Phone Number: 202-564-8828			
							FAX Number:			
Project Officer Name   Cynthia Bowie							Branch/Mail Code:			
_____ (Signature)                      (Date)							Phone Number: 202-564-7726			
							FAX Number:			
Other Agency Official Name							Branch/Mail Code:			
_____ (Signature)                      (Date)							Phone Number:			
							FAX Number:			
Contracting Official Name   Keith Westry							Branch/Mail Code:			
_____ (Signature)                      (Date)							Phone Number: 202-564-9863			
							FAX Number:			

**Statement of Work**

**Contract Number: EP-W-16-017  
Work Assignment Number: 1-06**

**Title: Chemical Hazard and Exposure Evaluation and Risk Management**

**Purpose:**

Increases the Level of Effort to 1,940 hours for more of the same type of work.

**I. Background:**

{No changes in this amendment.}

**II. Scope of Work:**

**Subtask 1. Work Plan and Task Management**

{No changes in this amendment.}

**Subtask 2. Quality Assurance Project Plan (QAPP)**

{No changes in this amendment.}

**Subtask 3. Rulemaking Support**

{No changes in this amendment.}

**Subtask 4. Meeting & Workshop Support**

{No changes in this amendment.}

**Subtask 5. Chemical Prioritization & Work Plan Chemicals**

{No changes in this amendment.}

**Subtask 6. Chemical Data Reporting (CDR)**

{No changes in this amendment.}

**Subtask 7. High Production Volume (HPV) Chemical Management**

{No changes in this amendment.}

**Subtask 8. Miscellaneous Hazard, Exposure, and Risk Analyses**

{No changes in this amendment.}



**III. Deliverables:**

**IV. Period of Performance:**

{No changes in this amendment.}

**V. Level of Effort:**

The level of effort described in this work assignment amendment shall not exceed 1,940 professional hours.

**VI. EPA Contacts:**

**Primary Contracting Officer Representative**

Jeffrey Taylor  
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**Alternate Contracting Officer Representative**

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[lloyd.tyler@epa.gov](mailto:lloyd.tyler@epa.gov)

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>		Work Assignment Number 1-07								
		<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:								
Contract Number EP-W-16-017	Contract Period   06/13/2016   To   06/12/2018 Base                      Option Period Number    1	Title of Work Assignment/SF Site Name Predictive Mathematical Modeli								
Contractor BATTELLE MEMORIAL INSTITUTE		Specify Section and paragraph of Contract SOW								
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval		Period of Performance  From   06/13/2017   To   06/12/2018								
Comments: Initiate work assignment for the new period of performance that begins on June 13, 2017. The contractor shall provide a workplan within 30 days of receipt of the work assignment.										
<input type="checkbox"/> Superfund                      Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
Note: To report additional accounting and appropriations date use EPA Form 1900-69A.										
SFO <input type="checkbox"/> (Max 2)										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:		LOE:						
06/13/2016 To 06/12/2018				0						
This Action:				1						
Total:				1						
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:		Cost/Fee		LOE:						
Cumulative Approved:		Cost/Fee		LOE:						
Work Assignment Manager Name    Tony Mcdonald  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 919-541-1476 FAX Number:				
Project Officer Name    Cynthia Bowie  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 202-564-7726 FAX Number:				
Other Agency Official Name  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: FAX Number:				
Contracting Official Name    Jody Gosnell  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 202-564-4353 FAX Number:				

**Battelle EPW16017**  
**Statement of Work**  
**Work Assignment 1-07**

**Title:** Predictive Mathematical Modeling of Water Contaminant Mixture Data

**Purpose:** The Work Assignment (WA) is to provide statistical expertise and modeling in support of mixtures and grouping research being conducted under the Safe and Sustainable Water Research (SSWR) National Research Program of the U.S. EPA. Specifically, this WAM is for statistical effort to: revise, based on new experimental design considerations, previously determined power calculations and sample size estimates for pre-determined effect magnitudes for health endpoints; extend the development and examination of approaches to discern the contributions of individual chemicals and chemical groups to the toxicity of a chemical mixture; conduct statistical analyses to examine the hypothesis that the toxicity of a group of chemicals can be predicted based on knowledge of the dose-response curves of the chemicals contained in the mixtures; to develop, where needed, novel approaches, methods and analyses for grouping chemicals and to enhance understanding of the joint toxic actions of groups of chemicals.; and, to provide expert consultation and advice in interpretation of results of analyses of chemical mixtures and groups.

**I. Background:**

While the need for toxicological research with both defined and complex mixtures of disinfection byproducts (DBPs) and other chemical contaminants of water is recognized, the lack of broadly-recognized appropriate statistical methods both to design appropriate experiments (e.g. power calculation methods to determine appropriate samples sizes to detect differences between treated groups and controls, if such differences exist) and the lack of broadly-recognized methods to determine when the effect of defined mixtures of chemicals deviates from that expected under an assumption of dose additivity, has hindered the ability to develop data needed by EPA to evaluate the potential human health risk that might be associated with exposure to the low levels of chemicals detected in water and to those chemicals formed or transformed during disinfection of water (DBPs, transformation DBPs).

Under the Safe and Sustainable Water National Research Program (SSWR), EPA is conducting a series of studies to understand the toxicity of groups of DBPs and transformation DBPs. DBPs and transformation DBPs are chemicals formed or transformed during the disinfection of drinking water. DBPs have been associated with adverse health effects through epidemiological and toxicologic studies. In addition to DBPs, candidate contaminant list (CCL) chemicals and chemicals of emerging concern (CECs) are interest, both individually and as groups. Studies at EPA are addressing different source waters and source water characteristics, different drinking waters (CCL and DBP focus) and wastewater treatments (CCL and DBP focus), with regard to the contaminants present and their concentrations, DBPs formed and their concentrations, and the relative toxic potency of the mixtures. Understanding those contaminants and contaminant groups that pose the greatest risks to human and ecological health will allow risk management

and remediation efforts to focus on those that provide the greatest reduction in risk. Integrating toxicological assessments into risk remediation and reduction research provides immediate and valuable feedback into those treatments/remedial activities that actually reduce health risk.

Predictive models for estimating the effects of contaminants groups will be used or developed/ revised where necessary and then used that have the ability to forecast the effects of contaminant groups from single chemical data, creating models that are predictive even when mixture composition changes (fewer chemicals in the mixture, more chemicals in the mixture, the mixing ratio changes as the mixture moves downstream or through the water system). The goal is to develop flexible and accurate predictive models for estimation for toxicity of contaminant groups that allow for addition and deletion of contaminants and varied specification of chemical concentrations (to enhance usefulness across a spectrum of situations).

## **II. Scope of Work**

The EPA WAM will identify the specific deliverables, corresponding delivery dates, and provide additional technical clarification/directives regarding the tasks of the work assignment listed below through written technical directives (except for tasks 1, 2, and 3). Each initial deliverable shall be provided to the EPA WAM in draft form for review and comment. The contractor shall incorporate procedures to ensure that these drafts completely document the methodologies; use appropriate assumptions; are accurate, complete, and as specified in the work assignment or written technical direction before providing them to the EPA. The contractor shall incorporate EPA review comments into revisions of the drafts. All drafts and final reports shall be approved by the EPA WAM. A work plan is required (Task 1) and a QA/QC plan is required (Task 2). CBI does not apply to this WAM. This work assignment relates to the current Statement of Work (SOW) of the contract.

### **1. Workplan**

The contractor shall prepare a work plan for each task in this work assignment before embarking on work on that particular task. The EPA WAM will inform the contractor of the EPA priorities with regard to conduct of each task. The work plan must provide the QA/QC elements will be observed during the conduct of this work assignment. These include that before conducting analyses the contractor shall provide the EPA the summary statistics of the data that are being planned for analysis, consisting of sample means, sample standard deviations and sample size for each dose group and that potential data quality issues be presented to EPA prior to proceeding further. The final report shall include a detailed description of all methods used; the results of any analyses conducted, including confidence intervals, statistical significance, multiple comparisons (as appropriate); for any data analyses conducted, summary statistics of the data generated from the final program used to analyze the data shall be provided with the summary statistics consisting of sample means, sample standard deviations and sample size for each dose group and the programs used for analysis.

### **2. Review Background Documentation**

The contractor shall review background documentation about the project. The EPA will provide publications and draft manuscripts that describe the Four Lab Study in detail, including all results to date. Additionally, the EPA will serve as a resource for relevant literature and background materials relevant to completion of the tasks.

### 3. Attend Kick-off Teleconferences

The contractor shall participate in a teleconference to address any questions that the contractor may have regarding the scope and goals of tasks 5, 6, and 7 and discuss the data, analytic requirements, relevant background information and available literature. A teleconference shall be conducted specific to each of tasks 5, 6, and 7. Additionally, the contractor shall prepare summary notes which clearly summarize the teleconferences.

### 4. Data Quality

The contractor shall assess databases to evaluate their data quality and integrity. The contractor shall identify outliers and questionable data by reviewing data listings and summaries, applying statistical methods, and using graphical methods. The contractor also shall review the data for missing values, censoring patterns, and appropriate units of measure (e.g., milligrams/liter). Prior to use of the data, the contractor shall supply the EPA with summary data for each dose group proposed for inclusion in the analysis, including the dose level, n, mean and standard deviation and identify the specific source of the data.

### 5. Experimental Design Recommendations

The contractor shall provide expert consultation in considering the impact of statistical power and data transformations for experiments involving defined and complex mixtures of chemicals. The contractor shall focus on the low dose / low effect region of the dose-response curve. The differential power associated with the logit and the arcsine square root transformation shall be considered for proportion data. The contractor shall refine, as necessary, power calculations and sample size estimates for pre-determined effect magnitudes for health endpoints in rats, for the priority endpoints of pup weight, prenatal loss, in vitro fertility, male and female sexual maturation, and cardiac defects. The contractor shall provide a report containing these results.

### 6. Determine Consistency with Dose Addition and Estimate the Contribution(s) of Individual Chemicals and Chemical Groups to the Toxicity of a Chemical Mixture and Provide Expert Consultation on Interpretation of Results integration dose addition and determination of contribution of component chemicals to mixture toxicity.

Using both data and reports furnished by the U.S. EPA, the contractor shall provide expert consultation with regard to mixtures analyses and, as directed, conduct statistical analyses to evaluate consistency with dose addition and estimate the contribution(s) of individual chemicals and chemical groups to the toxicity of a chemical mixture. The contractor shall also provide

expert consultation that provides insights into the interpretation of the results of statistical analyses of mixtures data. The first effort under this task shall consider in vivo toxicity data on individual trihalomethanes (chloroform, bromodichloromethane, chlorodibromomethane, bromoform) and the six possible binary combinations of these four chemicals. These data will be for examined for suitability of analysis by the expected component contribution score described by Hertzberg et al 2013 (*Toxicology*, 2013 (November) 313:134-144). The second effort consists of in vitro toxicity data on up to 10 haloacetic acids and haloacetic acid mixtures consisting of a varied number of chemicals, developed in vivo, in vitro and ex vivo assays. Additional efforts will involve data sets transmitted by the U.S. EPA and discussed in detail with the contractor. The contractor shall determine, for data sets provided by the EPA, whether predictions of mixture effect, made under dose addition assumptions and models or predictions of mixture toxicity made under independent action assumptions or models or predictions of mixture toxicity made using integrated addition methods (see for example Rider et al, 2008, Int J Androl. Apr;31(2):249-62) more closely approximate the observed mixture response. Data will be for examined for suitability of analysis by the expected component contribution score described by Hertzberg et al 2013 (*Toxicology*, 2013 (November) 313:134-144) or the method described by Parvez et al (submitted for publication and to be supplied by the US EPA). Where these or other approved by EPA approaches to determine the contribution of components or groups to mixture toxicity are found suitable, these analyses shall be conducted by the contractor.

7. Review peer-reviewed publications that describe the analysis of mixtures data and determine the suitability of the experimental design, the analysis and the conclusions

It is well known that many mixtures experiments that have been published in the peer-reviewed literature are lacking in design, in analysis or in interpretation, such that the conclusions drawn from the studies may not be appropriate. The contractor shall review selected studies provided by the EPA and examine them for appropriateness of experimental design, statistical analysis and the interpretation of the results provided in the publications. Where feasible the data will be analyzed by alternative methods, with methods subject to approval by the EPA. Also, where possible, quantitative metrics of deviation from additivity will be derived, in those cases where deviation from additivity is detected.

8. Develop computer programs

The contractor shall ensure that all databases, computer programs, and the corresponding documentation developed under this contract are accessible to the EPA Project Officer, the EPA WAM, and persons authorized by them. The contractor shall provide this computer programming support to technically support the statistical analysis specified in other areas of this statement of work. All computer programs shall be well documented internally to facilitate EPA's review. Furthermore, the contractor shall use SAS, the Agency standard software for statistical analysis.

9. Internal Documentation

The contractor shall internally document all assumptions, data sources, databases, procedures, statistical analyses, and computer programming code so that results can be replicated even if the originating staff members are no longer available. The contractor shall provide access to this internal documentation upon request by the EPA WAM. This documentation shall provide the foundation of the documentation of the products to be produced in the other areas of this Work Assignment (see #10)

#### 10. Prepare documentation

The contractor shall provide documentation for products in the other areas of this Work Assignment. The contractor shall provide documentation in computer files, and in hardcopy, upon specific request. The contractor shall incorporate EPA comments into revisions of the draft documentation. In all cases, the statistical algorithms and data used to generate results shall be provided electronically as well as in the appendix of the draft and final reports. The documentation shall include all assumptions, data sources, databases, procedures, statistical analyses, and computer programming code used in accomplishment of the work effort.

In any documentation, the contractor shall clearly specify the methods, procedures, considerations, assumptions, relevant citations, data sources, and data that support the results and any recommendations. The contractor also shall document alternative methods, procedures, and assumptions that the contractor considered in the statistical analysis. Further, the documentation shall be labeled with the name of the contractor, the EPA contract number (EPW16017) and the work assignment number (1-07).

**IV. Period of Performance:** This work assignment will start on the date of the contracting officer's signature and extend through the period of performance of the contract.

**V. Estimated Level of Effort Hours:** 286

#### **VI. EPA contacts**

##### **Work Assignment Manager:**

Tony McDonald  
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##### **Alternate Work Assignment Manager:**

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 National Health and Environmental Effects Research Laboratory  
 U.S. Environmental Protection Agency  
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 e-mail: Hughes.MichaelF@epa.gov

## V. Deliverables and Schedule

The following is a list of the deliverables required under this Task Order.

<u>Task</u>	<u>Deliverable</u>	<u>Date</u>
1	Initial Work plan	Due 30 days following receipt of Work Assignment (WA)
2	Knowledge about previous statistical work (i.e., contractor needs to read background materials).	Start upon receipt of the WA
3	Kick-Off Teleconferences for Tasks 5 and 6	At the beginning of work on each task at a time mutually agreement to EPA and the contractor. First Teleconference to take place within 4 weeks of receipt of the WA
4	Electronic files with the statistical analyses and quality assurance evaluations, computer programs, draft and final documentation (memoranda, reports) of results and methods used. Hardcopies, if requested in technical direction.	Following technical direction from the WA. Revisions delivered as specified in technical directions.
5	Experimental Design Recommendations	Revisions delivered as specified in technical directions. Periodic Consultation, with Draft Reports due 30 days after request delivered and subsequent kick-off teleconferences*



<u>Task</u>	<u>Deliverable</u>	<u>Date</u>
6	Determine Consistency with Dose Addition and Estimate the Contribution(s) of Individual Chemicals and Chemical Groups to the Toxicity of a Chemical Mixture and Provide Expert Consultation on Interpretation of Results	Revisions delivered as specified in technical directions. Periodic Consultation, with Draft Reports due 30 days after request delivered and subsequent kick-off teleconferences*
7	Review peer-reviewed publications that describe the analysis of mixtures data and determine the suitability of the experimental design, the analysis and the conclusions.	Revisions delivered as specified in technical directions. Periodic Consultation, with Draft Reports due 45 days after request delivered and subsequent kick-off teleconferences*
8	Briefings on Results of Tasks 5, 6, and 7	Within 3 weeks of contractor providing the draft reports as specified for each task.
9	Computer programs and Documentation	As identified for other areas of the SOW.

\* These dates may be modified by technical direction, rather than requiring workplan modification.

## **VI. OTHER REQUIREMENTS**

The contractor shall provide written notification to the contracting officer, project officer, and work assignment manager when 75 percent of the hours and/or funds have been spent on this work assignment.

The contractor also shall immediately contact the EPA WAM to discuss any problems that may adversely affect the work on this work assignment.

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>						Work Assignment Number 1-07				
						<input type="checkbox"/> Other <input checked="" type="checkbox"/> Amendment Number: 000001				
Contract Number EP-W-16-017			Contract Period   06/13/2017   To   06/12/2018 Base                      Option Period Number      1			Title of Work Assignment/SF Site Name Predictive Mathematical Model				
Contractor BATTELLE MEMORIAL INSTITUTE					Specify Section and paragraph of Contract SOW					
Purpose: <input type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input checked="" type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance  From   06/13/2017   To   06/12/2018				
Comments: Revised SOW to include additional tasks. Contractor shall provide work plan 30 days after receipt of work assignment amendment.										
<input type="checkbox"/> Superfund    Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
SFO <input type="checkbox"/> Note: To report additional accounting and appropriations date use EPA Form 1900-69A. (Max 2)										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:				LOE: 1				
06/13/2017 To 06/12/2018						0				
This Action:						1				
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:				Cost/Fee		LOE:				
Cumulative Approved:				Cost/Fee		LOE:				
Work Assignment Manager Name    Tony McDonald  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 919-541-1476 FAX Number:				
Project Officer Name    Tyrone Thomas  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 202-564-3121 FAX Number:				
Other Agency Official Name  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: FAX Number:				
Contracting Official Name    Jody Gosnell  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 202-564-4353 FAX Number:				

## **Amendment of Work**

**Contract Number:** EP-W-16-017

**Work Assignment:** 03-1

**Amendment Number:** 1

**Title:** Technical Support for PCB Permits and Document Development

### **Background**

This project adds *Task 7: PCB Database Entry* to the work assignment and moves part of the remaining funds and hours from *Task 5: Finalization of “PCB Guidance” and Response to Comments* to the new *Task 7*.

The reason for doing so is that EPA’s management review of the PCB guidance is taking longer than expected and may not be completed before the work assignment ends. Therefore, EPA’s management has decided to shift part of the remaining funds and hours into the new *Task 7*.

### **Scope of Work**

Several Regions have either an *Access* database or *Excel* spreadsheet containing their PCB notifications and PCB approvals data. Since EPA is moving to a national PCB database in *RCRAInfo*, there is a need to re-enter all the data from the Regional databases/spreadsheets into *RCRAInfo*. In particular, Region 1’s database contains 757 entries and about 20 fields that are common to both databases. This work assignment amendment seeks to add a *Task 7* to the work assignment to have the Contractor perform the data entry from the Regional databases/spreadsheets into *RCRAInfo*, beginning with the Region 1 database.

### **Tasks**

#### **Task 1. Task Management**

The Contractor shall prepare and submit a work plan. Work under this task shall include participating in project update meetings/teleconferences, preparing the monthly progress reports and other task management.

#### **Task 7. PCB Database Entry - NEW**

The Contractor will enter as much of the PCB data from the Regional databases/spreadsheets into *RCRAInfo*, within the existing funding limits. Contractor will begin entering data from the Region 1 database, beginning with the most recent approvals/notification data. When more funding becomes available, Contractor will continue entering the remaining data from the Region 1 database as well as other Regional database/spreadsheets as they become available. Contractor will enter the data manually (i.e., typing) and perform a data entry quality assurance check (i.e., every field entered for every site will be double checked for correctness by a separate individual).

This work assignment relates to Tasks III, IV, and V of the current contract statement of work.

### **Deliverables**

<b>Deliverable</b>	<b>Schedule</b>
<b>Task 1:</b> Task Management	Within 30 days of issuance of Work Assignment Amendment, the Contractor shall submit a Work Plan for review and acceptance.
<b>Task 7:</b> PCB Database Entry	Upon receipt of databases from the Regions, the Contractor shall enter the data into RCRAInfo within 10 days.

### **Period of Performance**

This work assignment will start on the date of the contracting officer's signature and extend through June 13, 2018.

### **Level of Effort**

The estimated level of effort for this requirement is: **120 hours**. *NOTE: these hours DO NOT increase the level of funding but are part of the remaining 163.50 hours left in the work assignment per the December 2017 invoice.*

### **EPA Contacts**

#### **Work Assignment Manager**

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#### **Alternate Work Assignment Manager**

Jenny McLeod  
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Washington, DC 20460  
Phone: (703) 308-8459

#### **Courier Service Address:**

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2777 S. Crystal Drive  
Room S-6217  
Arlington, VA 22202

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>						Work Assignment Number 1-08				
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:				
Contract Number EP-W-16-017			Contract Period   06/13/2016   To   06/12/2018 Base                      Option Period Number      1			Title of Work Assignment/SF Site Name				
Contractor BATTELLE MEMORIAL INSTITUTE					Specify Section and paragraph of Contract SOW					
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance  From   06/13/2017   To   06/12/2018				
Comments: Initiate work assignment for the new period of performance that begins on June 13, 2017. The contractor shall provide a workplan within 30 days of receipt of the work assignment.										
<input type="checkbox"/> Superfund                      Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
SFO <input type="checkbox"/> Note: To report additional accounting and appropriations date use EPA Form 1900-69A. (Max 2)										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:                      Cost/Fee:                      LOE: 06/13/2016   To   06/12/2018										
This Action:  										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:                      Cost/Fee                      LOE:										
Cumulative Approved:                      Cost/Fee                      LOE:										
Work Assignment Manager Name    Cynthia Bowie  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 202-564-7726 FAX Number:			
Project Officer Name    Cynthia Bowie  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 202-564-7726 FAX Number:			
Other Agency Official Name  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: FAX Number:			
Contracting Official Name    Jody Gosnell  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 202-564-4353 FAX Number:			

**Contract Number: EP-W-16-017**

**Work Assignment Number: 1-08**

**Change Number: 0**

**Title: RRP Lead Outreach to Contractors**

## **I. Purpose and Background**

This work assignment is a continuation of WA 0-08 on Contract Number EP-W-16-017. This Work Assignment continues and expands upon the work initiated in WA 0-08 under Contract EP-W- 16-017 and provides technical support for the implementation of the Renovation, Repair and Painting Program. No work shall be repeated that was previously completed in WA 0-08.

Section 402(c) of TSCA authorizes EPA to promulgate regulations governing renovation activities conducted in homes built before 1978 that produce a lead-based paint hazard. EPA promulgated these regulations at 40 CFR part 745, Subpart E.

Under TSCA Section 404, EPA may authorize any State to administer and enforce the standards, regulations, or other requirements established under TSCA Sections 402 if the State has a program that is at least as protective of human health and the environment as the program specified in TSCA and that provides adequate enforcement. EPA's implementing regulations can be found at 40 CFR part 745, Subpart Q.

Section 404(h) of TSCA requires EPA to implement and enforce a federal lead based paint program in all States and Tribal areas that do not have an authorized program. EPA is permitted to use State and Tribal Assistance Grant funds to support implement the programs. (See 40 CFR 35.116, and 40 CFR 35.516.) Under this work assignment, EPA is seeking to increase the number of renovation contractors with RRP firm certification and/or those that take RRP training from an EPA authorized training provider.

## **II. Scope of Work**

The Contractor shall:

- ☐ Continue to develop a program to encourage non-certified RRP firms to become certified or to renew their RRP firm certification in El Paso, TX, Denver, CO, Oakland, CA, Memphis, TN, Kansas City, MO, and Baltimore. Effort may involve:
  - Finalizing graphic ads, post cards, flyers, fact sheets, web banners, mailings, etc. for non-certified RRP firms developed under WA 0-08 on Contract Number EP-W-16-017 for each of the 6 cities identified above.
  - Printing and placing ads for each of the 6 cities identified above in this WA.
- ☐ Identify, reserve space, and pay (if required) for a venue for at least one lead outreach informational session event for non-certified RRP contractors in each city identified in WA 0-08 on Contract Number EP-W-16-017 to include but not limited to radio and TV interviews, town hall and local meetings or events. The Contractor shall work with the EPA WAM to determine what the event will be held in each city. This effort will be done in coordination with WA 0-02 on Contract Number EP-W-16-017 in the same cities.

### **III. Deliverables:**

Summary of Work – The Contractor shall submit to the EPA WAM a report providing statistics on the activity for the contract period. The letter shall summarize the work completed and shall include what outreach activities occurred and the number of people reached. In addition, the report will include:

- A description of ads printed for each outreach session in each of the cities.
- A description of the actual outreach event held in each of the cities, including the name, location of the venue, date, and time.
- A description of the number of firms contacted and sources used to develop list of renovation firms to contact.
- An analysis of which outreach messages and delivery mechanism were most and least effective.

**A work plan is required.**

**A Quality Assurance Project Plan is not required since no data collection is required.**

**CBI does not apply.**

This work assignment relates to Tasks III and IV of the current Statement of Work (SOW) of the contract.

**IV. Period of Performance: June 13, 2017 – June 12, 2018**

**V. Estimated Level of Effort Hours: 150**

### **VI. EPA Contacts:**

#### Work Assignment Manager:

Darlene Leonard

US EPA National Program Chemicals Division  
Program Assessment and Outreach Branch (7404T)  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460 Phone: 202-566-1859

#### Deputy Work Assignment Manager:

Julie Shannon

US EPA National Program Chemicals Division  
Program Assessment and Outreach Branch (7404T)  
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<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>						Work Assignment Number 1-10				
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:				
Contract Number EP-W-16-017			Contract Period   06/13/2016   To   06/12/2018 Base                      Option Period Number      1			Title of Work Assignment/SF Site Name New Chemical Program Support				
Contractor BATTELLE MEMORIAL INSTITUTE					Specify Section and paragraph of Contract SOW					
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance  From   06/13/2016   To   06/12/2018				
Comments: Initiating a work assignment on EPW16017. The contractor shall provide a work plan within 30 days of receipt of this work assignment.										
<input type="checkbox"/> Superfund                      Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
SFO <input type="checkbox"/> Note: To report additional accounting and appropriations date use EPA Form 1900-69A. (Max 2)										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:				LOE: 0				
06/13/2016 To 06/12/2018										
This Action:						0				
Total:						0				
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:				Cost/Fee		LOE:				
Cumulative Approved:				Cost/Fee		LOE:				
Work Assignment Manager Name    Monica Miller  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 202-564-6473 FAX Number:				
Project Officer Name    Tyrone Thomas  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 202-564-3121 FAX Number:				
Other Agency Official Name    Jacqueline Sayles  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 919-541-4826 FAX Number:				
Contracting Official Name    Jody Gosnell  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 202-564-4353 FAX Number:				



**Contract Number: EP-W-16017**

**Work Assignment Number: 1-10**

**Title: New Chemical Program Support**

**Purpose:**

This work assignment will provide support the New Chemical Program (NCP) in processing of Pre Manufacturer Notices (PMNs). No work performed under previous work assignments will be duplicated under this work assignment.

**I. Background:**

This work assignment, entitled *New Chemicals Program Support*, is being developed to provide EPA with support to expedite the processing of the Pre Manufacturer Notice (PMN) to reduce the backlog brought about by the enactment of the Frank R. Lautenberg Chemical Safety for the 21<sup>st</sup> Century Act. This law became effective immediately upon being signed on June 22, 2016. The activities listed below will reduce processing times for tracking case status, for developing Letters and Consent Orders, and for writing Significant New Use Rules (SNURs). Completion of all of these activities and their implementation by the NCP should be possible within 3-4 months after issuance of new work assignments under existing contract vehicles.

EPA's New Chemicals Program is required to review and make an affirmative determination of risk on new chemical substances submitted for evaluation in premanufacture notices (PMNs) and significant new use notices (SNURs) before manufacturing can commence. The review evaluates a new chemical substance given the information provided by the submitter of the PMN and the information readily available to EPA to determine if the new chemical substance poses a risk to human health or the environment. This review includes an evaluation of physical and chemical characteristics of the substance, the fate, the human health and environmental hazards and exposures, and risk management to make the affirmative determination of risk. Once the determination is made EPA may regulate the manufacturing, processing and or use of a new chemical substance through a Consent Order and/or Significant New Use Rule (SNUR) which require manufacturers/importers to alert EPA of any new uses of the new chemical substance.

**II. Scope of Work:**

**Subtask 1. Work Plan and Task Management**

The contractor shall prepare and submit a work plan in accordance with the requirements of this contract. Work under this subtask will include participating in conference calls, preparing monthly progress reports, and other task management.

**Subtask 2. Quality Assurance Project Plan (QAPP)**

The contractor shall create a Quality Assurance Project Plan (QAPP) that documents the planning, implementation, and assessment procedures for subtasks 3 and 4 in this SOW, as well as any specific quality assurance and quality control activities. The QAPP integrates all of the technical and quality aspects of the project in order to provide a blueprint for obtaining the type and quality of environmental data and information needed for a specific decision or use. All work performed or funded by EPA that involves the acquisition of environmental data must have an approved QAPP. Details for developing a QAPP can be found at: <https://www.epa.gov/sites/production/files/2015-06/documents/g5-final.pdf> and

the contractor shall be responsible for the development of, and any revisions to, the QAPP. Revisions to the QAPP must be made prior to beginning environmental data activities.

#### **Subtask 3. Document/Data Entry**

Complete scanning and entering into PMN Gold all Consent Orders (sanitized and CBI), all CCD Briefing Papers and other CCD-generated documents. All documents scanned into PMN Gold soon will be migrated into phase 1 Enterprise Management System (EMS) by the Information Management Division (IMD).

#### **Subtask 4. Document Sanitization**

Sanitize documents by removing Confidential Business Information CBI from Risk Assessment Division (RAD) Section 5 Risk Assessment documents. This will increasingly be asked for by companies as EPA eliminates the practice of sending Action Letters immediately drafting Consent Orders to be sent to PMN submitters upon finalization of the affirmative risk finding and development of risk management options.

#### **Subtask 5. Tracking Support**

Complete simple spreadsheet created by NCP to track progress of eliminating the back log of cases as well as tracking the completion of information requests sent by PMs to be completed by RAD. PMs will provide the status/ milestones to be tracked and added to the spreadsheet.

#### **Subtask 6. Consent Order and SNUR Development**

Provide support in developing draft TSCA section 5(e) Consent Orders and SNURs.

After collecting documentation from the Program Manager (PM) to include briefing papers, draft action letters, and other correspondence as well as data and information in PMN Gold and submitted PMNs, draft Consent Orders and SNURS. Drafts will be developed from boiler plates following instructions and using the information collected. After Draft is completed review with PM and prepare printed document for review and signature.

### **III. Deliverables:**

Subtask 1.	The contractor shall prepare and submit the work plan in accordance with contract requirements.	
Subtask 2.	Quality Assurance Project Plan (QAPP) <ul style="list-style-type: none"><li>• Initial QAPP</li><li>• Revised QAPP(s)</li></ul>	<ul style="list-style-type: none"><li>• 10 days after WA begins</li><li>• Prior to work on environmental data activities</li></ul>
Subtask 3.	Document/Data Entry	At WAM's Request.
Subtask 4.	Document Sanitization	At WAM's Request.
Subtask 5.	Tracking Support	At WAM's Request.

Subtask 6.	Consent Order and SNUR Development	At WAM's Request.
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- **EPA will approve the work plan within 30 days.**
- **A Quality Assurance Project Plan (QAPP) is required.** The contractor shall implement a quality system that meets ANSI standard E4-2014 and prepare a QAPP following OPPT/EPA guidelines. No work on the conduct of environmental data operations can begin until EPA approval of the QAPP is obtained.
- **CBI does apply.**
- **Contractor personnel shall at all times identify themselves as contractor employees, and shall not present themselves as EPA employees. Furthermore, they shall not represent views of the U.S. Government, EPA, or its employees. In addition, the contractor shall not engage in inherently governmental activities, including but not limited to actual determination of EPA policy and preparation of documents on EPA letterhead other than routine correspondences.**

#### **IV. Period of Performance:**

This Work Assignment will start with the date of the Contracting Officer's signature and extend through - June 12, 2018.

#### **V. Level of Effort:**

The estimated level of effort for this work assignment is 1,180 professional hours.

#### **VI. EPA Contacts:**

##### **Primary Contracting Officer Representative**

Monica Miller  
WJC East Building, Rm 4133-D, MC 7405M  
1200 Penn. Ave, NW, Washington, DC 20460  
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[miller.monica@epa.gov](mailto:miller.monica@epa.gov)

##### **Alternate Contracting Officer Representative**

Christopher Buckley  
WJC East Building, Rm 4121-K, MC 7405M  
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[Buckley.christopher@Epa.gov](mailto:Buckley.christopher@Epa.gov)

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>						Work Assignment Number 1-10				
						<input type="checkbox"/> Other <input checked="" type="checkbox"/> Amendment Number: 000001				
Contract Number EP-W-16-017			Contract Period 06/13/2017 To 06/12/2018			Title of Work Assignment/SF Site Name				
			Base                      Option Period Number                      1			New Chemical Support				
Contractor BATTELLE MEMORIAL INSTITUTE					Specify Section and paragraph of Contract SOW					
Purpose: <input type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input checked="" type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval					Period of Performance  From 06/13/2016 To 06/12/2018					
Comments: Amending work assignment to add additional Sub Task 7, 8, and 9. The contractor shall provide a work plan within 30 days of receipt of this amendment.										
<input type="checkbox"/> Superfund                      Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
SFO <input type="checkbox"/> (Max 2)                      Note: To report additional accounting and appropriations date use EPA Form 1900-69A.										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period: 06/13/2017 To 06/12/2018                      Cost/Fee:                      LOE:										
This Action:										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:                      Cost/Fee                      LOE:										
Cumulative Approved:                      Cost/Fee                      LOE:										
Work Assignment Manager Name    Monica Miller  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 202-564-6473 FAX Number:			
Project Officer Name    Tyrone Thomas  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 202-564-3121 FAX Number:			
Other Agency Official Name  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: FAX Number:			
Contracting Official Name    Keith Westry  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 202-564-9863 FAX Number:			

**Contract Number: EP-W-16017**

**Work Assignment Number: 1-10 Amendment.**

**Title: New Chemical Program Support**

**Purpose:**

This work assignment will provide support the New Chemical Program (NCP) in processing of Pre Manufacturer Notices (PMNs). No work performed under previous work assignments will be duplicated under this work assignment. This amendment adds Subtasks 7. Pre Notice Communication, 8. Ad Hoc Committee and 9. Miscellaneous Administrative Support. There is no change for Subtasks 1-6.

**I. Background:**

This work assignment, entitled *New Chemicals Program Support*, is being developed to provide EPA with support to expedite the processing of the Pre Manufacturer Notice (PMN) to reduce the backlog and implement new requirements brought about by the enactment of the Frank R. Lautenberg Chemical Safety for the 21<sup>st</sup> Century Act. This law became effective immediately upon being signed on June 22, 2016. The activities listed below will reduce processing times for tracking case status, for developing Letters and Consent Orders, and for writing Significant New Use Rules (SNURs). and will provide administrative assistance needed to implement new or enhanced program activities being implemented as a result of the new law.

EPA's New Chemicals Program is required to review and make an affirmative determination of risk on new chemical substances submitted for evaluation in premanufacture notices (PMNs) and significant new use notices (SNUNs) before manufacturing can commence. The review evaluates a new chemical substance given the information provided by the submitter of the PMN and the information readily available to EPA to determine if the new chemical substance poses a risk to human health or the environment. This review includes an evaluation of physical and chemical characteristics of the substance, the fate, the human health and environmental hazards and exposures, and risk management to make the affirmative determination of risk. Once the determination is made EPA may regulate the manufacturing, processing and or use of a new chemical substance through a Consent Order and/or Significant New Use Rule (SNUR) which require manufacturers/importers to alert EPA of any new uses of the new chemical substance. Pre Notice Communication is an effort for Program staff to work with potential PMN submitters to provide information and guidance to improve the quality and contents of a PMN which should help make the review process more efficient.

**II. Scope of Work:**

**Subtask 1. Work Plan and Task Management**

The contractor shall prepare and submit a work plan in accordance with the requirements of this contract. Work under this subtask will include participating in conference calls, preparing monthly progress reports, and other task management.

**Subtask 2. Quality Assurance Project Plan (QAPP)**

The contractor shall create a Quality Assurance Project Plan (QAPP) that documents the planning, implementation, and assessment procedures for subtasks 3 and 4 in this SOW, as well as any specific quality assurance and quality control activities. The QAPP integrates all of the technical and quality

aspects of the project in order to provide a blueprint for obtaining the type and quality of environmental data and information needed for a specific decision or use. All work performed or funded by EPA that involves the acquisition of environmental data must have an approved QAPP. Details for developing a QAPP can be found at: <https://www.epa.gov/sites/production/files/2015-06/documents/g5-final.pdf> and the contractor shall be responsible for the development of, and any revisions to, the QAPP. Revisions to the QAPP must be made prior to beginning environmental data activities.

### **Subtask 3. Document/Data Entry**

Complete scanning and entering into PMN Gold all Consent Orders (sanitized and CBI), all CCD Briefing Papers and other CCD-generated documents. All documents scanned into PMN Gold soon will be migrated into phase 1 Enterprise Management System (EMS) by the Information Management Division (IMD).

### **Subtask 4. Document Sanitization**

Sanitize documents by removing Confidential Business Information CBI from Risk Assessment Division (RAD) Section 5 Risk Assessment documents. This will increasingly be asked for by companies as EPA eliminates the practice of sending Action Letters immediately drafting Consent Orders to be sent to PMN submitters upon finalization of the affirmative risk finding and development of risk management options.

### **Subtask 5. Tracking Support**

Complete simple spreadsheet created by NCP to track progress of eliminating the back log of cases as well as tracking the completion of information requests sent by PMs to be completed by RAD. PMs will provide the status/ milestones to be tracked and added to the spreadsheet.

### **Subtask 6. Consent Order and SNUR Development**

Provide support in developing draft TSCA section 5(e) Consent Orders and SNURs.

After collecting documentation from the Program Manager (PM) to include briefing papers, draft action letters, and other correspondence as well as data and information in PMN Gold and submitted PMNs, draft Consent Orders and SNURS. Drafts will be developed from boiler plates following instructions and using the information collected. After Draft is completed review with PM and prepare printed document for review and signature.

### **Subtask 7. Pre Notice Communication Program (New Task)**

Provide support in Scanning Historical files containing information and notes on approximately 4000 Pre Notice Communications including correspondence and meetings. The files will be used to modify and populate an existing database with existing and new metadata requested by the WAM.

### **Subtask 8. New Chemicals Ad Hoc Committee Support (New Task)**

Provide support to the Ad Hoc committee on New Chemicals by drafting decision documents using a template and populating with data and information from Chemical Control Division briefing papers and Risk Assessment Division documents supporting review of New Chemicals. Attend Ad Hoc New

Chemicals Prep meetings currently being held twice weekly and tracking progress of PMNs thru the Committee process.

#### **Subtask 9. Miscellaneous Administrative Support (New Task)**

Provide miscellaneous support to the New Chemicals Program as needed, which may include preparation, scanning, shredding, uploading etc. of documents and files, tracking progress of work effort, database creation, population and maintenance and completing information requests.

### **III. Deliverables:**

Subtask 1.	The contractor shall prepare and submit the work plan in accordance with contract requirements.	
Subtask 2.	Quality Assurance Project Plan (QAPP) <ul style="list-style-type: none"><li>• Initial QAPP</li><li>• Revised QAPP(s)</li></ul>	<ul style="list-style-type: none"><li>• 10 days after WA begins</li><li>• Prior to work on environmental data activities</li></ul>
Subtask 3.	Document/Data Entry	At WAM's Request.
Subtask 4.	Document Sanitization	At WAM's Request.
Subtask 5.	Tracking Support	At WAM's Request.
Subtask 6.	Consent Order and SNUR Development	At WAM's Request.
Subtask 7.	Pre Notice Communication	At WAM's Request.
Subtask 8.	Ad Hoc Committee	At WAM's Request.
Subtask 9.	Miscellaneous Administrative Support	At WAM's Request.

- **EPA will approve the work plan within 30 days.**
- **A Quality Assurance Project Plan (QAPP) is required.** The contractor shall implement a quality system that meets ANSI standard E4-2014 and prepare a QAPP following OPPT/EPA guidelines. No work on the conduct of environmental data operations can begin until EPA approval of the QAPP is obtained.
- **CBI does apply.**
- **Contractor personnel shall at all times identify themselves as contractor employees, and shall not present themselves as EPA employees. Furthermore, they shall not represent views of the U.S. Government, EPA, or its employees. In addition, the contractor shall not engage in inherently governmental activities, including but not limited to actual determination of EPA policy and preparation of documents on EPA letterhead other than routine correspondences.**

### **IV. Period of Performance:**

This Work Assignment will start with the date of the Contracting Officer's signature.

### **V. Level of Effort:**

The estimated level of effort for this work assignment is 1,280 professional hours. This modification increases the level of effort by 870 hours to a total of 2150 hours.

**VI. EPA Contacts:**

**Primary Contracting Officer Representative**

Monica Miller  
WJC East Building, Rm 4133-D, MC 7405M  
1200 Penn. Ave, NW, Washington, DC 20460  
Phone: (202) 564-6473  
[miller.monica@epa.gov](mailto:miller.monica@epa.gov)

**Alternate Contracting Officer Representative**

Christopher Buckley  
WJC East Building, Rm 4121-K, MC 7405M  
1200 Penn. Ave, NW, Washington, DC 20460  
Phone: (202) 564-4817  
[Buckley.christopher@Epa.gov](mailto:Buckley.christopher@Epa.gov)



<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>						Work Assignment Number 1-11				
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:				
Contract Number EP-W-16-017			Contract Period   06/13/2016   To   06/12/2018 Base                      Option Period Number      1			Title of Work Assignment/SF Site Name New Chemical Support for SNURS				
Contractor BATTELLE MEMORIAL INSTITUTE					Specify Section and paragraph of Contract SOW					
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance  From   06/13/2017   To   06/12/2018				
Comments: Initiating a Work Assignment on EPW16017. The contractor shall provide a work plan within 30 days of receipt of the work assignment										
<input type="checkbox"/> Superfund                      Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
SFO <input type="checkbox"/> Note: To report additional accounting and appropriations date use EPA Form 1900-69A. (Max 2)										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:		LOE:						
06/13/2016 To 06/12/2018				0						
This Action:				0						
Total:				0						
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:				Cost/Fee		LOE:				
Cumulative Approved:				Cost/Fee		LOE:				
Work Assignment Manager Name   Martha Miller  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 202-564-0295 FAX Number:				
Project Officer Name   Tyrone Thomas  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 202-564-3121 FAX Number:				
Other Agency Official Name   Jacqueline Sayles  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 919-541-4826 FAX Number:				
Contracting Official Name   Jody Gosnell  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 202-564-4353 FAX Number:				

**Contract Number: EP-W-16017**

**Work Assignment Number: 1-11**

**Title: New Chemical Program Support for Significant New Use Rules, Consent Orders, and Other New Chemical Regulatory Activities**

**Purpose:**

This work assignment will provide support the New Chemical Program (NCP) in collecting, formatting and data entry into the Chemical Control Divisions Consent Order/SNUR database. No work performed under previous work assignments will be duplicated under this work assignment.

**I. Background:**

This work assignment, entitled *New Chemical Program Support for Significant New Use Rules, Consent Orders, and Other New Chemical Regulatory Activities*, is being developed to provide EPA with support for making TSCA regulatory actions more readily available to other government agencies, as well as the public.

The Premanufacture Notice (PMN) program is mandated by Section 5 of the Toxic Substances Control Act (TSCA). EPA's New Chemicals Program (NCP), which is part of the Office of Pollution Prevention and Toxics (OPPT), is responsible for coordinating the review process of Premanufacture Notice (PMN) submissions and identifying new substances that require regulatory action. The New Chemicals Management Branch (NCMB) in the Chemical Control Division (CCD) of OPPT is responsible for the risk management of new chemicals.

During the Agency's review period, EPA must determine whether the chemical should be regulated because it may present an unreasonable risk to human health or the environment. One method of regulation is for the EPA to enter into a Consent Order with the Company (under Section 5(e) of TSCA), which allows production of the chemical to proceed under specific restrictions. Under the Expedited Follow-up Rule effective October 10, 1989, when a 5(e) Consent Order is issued for a new chemical substance, EPA is obligated to issue a Significant New Use Rule (SNUR) within a limited period of time. Other deadlines exist for previously issued 5(e) Orders and for new chemical substances that pass through new chemical review but are identified as non-5(e) SNUR candidates. The purpose of the Significant New Use Rule (SNUR) is to extend regulation of new chemicals beyond the PMN submitter.

CCD will utilize information contained in the CCD Consent Order/SNUR database to create an MS Access Database to populate the Chemview system for generation of Chemview Templates. All information uploaded into the Chemview system would not contain Confidential Business Information (CBI). Chemview will be the program to make TSCA regulatory actions more readily available to other government agencies, as well as the public.

**II. Scope of Work:**

**Subtask 1. Work Plan and Task Management**

The contractor shall prepare and submit a work plan in accordance with the requirements of this contract. Work under this subtask will include participating in conference calls, preparing monthly progress reports, and other task management.

## **Subtask 2. Quality Assurance Project Plan (QAPP)**

The contractor shall create a Quality Assurance Project Plan (QAPP) that documents the planning, implementation, and assessment procedures in this SOW, as well as any specific quality assurance and quality control activities. The QAPP integrates all of the technical and quality aspects of the project in order to provide a blueprint for obtaining the type and quality of environmental data and information needed for a specific decision or use. All work performed or funded by EPA that involves the acquisition of environmental data must have an approved QAPP. Details for developing a QAPP can be found at: <https://www.epa.gov/sites/production/files/2015-06/documents/g5-final.pdf> and the contractor shall be responsible for the development of, and any revisions to, the QAPP. Revisions to the QAPP must be made prior to beginning environmental data activities.

## **Subtask 3. Collection of Supporting Documents**

The contractor shall initiate collection of supporting and source documents including Federal Register Notices and TSCA Section 5(e) Consent Orders for PMNs identified by the WAM in written technical direction. The Contractor shall utilize all available resources, including the Documentum and CIS databases - electronic version of the files from the Confidential Business Information Center (CBIC), PMN Gold Workflow System, the CBI LAN, individual network directories, hard copy files, etc., for collection of the documents. The documents collected in this manner do not contain CBI, however, they are located in a CBI environment. In those instances, when the documents are not located in a CBI environment, they may be located on public websites including, but not limited to Regulations.gov, Pubchem, and HeinOnline.

The contractor shall create a pdf copy of all identified documents for which pdf files are not already available. If the documents are not available electronically, the Contractor shall create a scanned image of the document and convert it to a text searchable pdf format. The EPA Work Assignment Manager (WAM) shall provide guidance on naming and storage of the collected documents. The Contractor shall notify the Work Assignment Manager (WAM) of any files which are missing.

## **Subtask 4. Formatting of Supporting Documents**

The contractor shall provide technical assistance to the WAM in formatting of supporting documents as Adobe pdfs. The WAM shall provide written guidance on the formatting requirements, including suitable metadata requirements for publication in the Chemview system. Formatted pdf documents must be text searchable to accommodate the functionality within the Chemview system.

The contractor shall track the progress of completion of these formatted documents and verify that completed reports have been posted to the correct location. For the signed 5(e) Consent Orders, the contractor shall notify the WAM of any delays in completion of the reports, and to obtain any sanitized orders that are not available. As the EPA contact, the WAM is responsible for certifying that all formatted documents are suitable for transmission to the Chemview system.

## **Subtask 5. CCD Consent Order/SNUR database**

The contractor shall use the collected 5(e) Consent Orders and Federal Register Notices for all SNURs to review and populate tables within the CCD Consent Order/SNUR database. All identified chemicals shall be entered into the system using the guidance documents provided by the WAM. Process will include the completion of a data worksheet, entry of the required data into the appropriate data tables, and

QA/QC of the information for quality assurance purposes according to the approved QAPP. Any identified missing or questionable content shall be reported to the WAM. Using the information contained in the database, the contractor shall create MS Access database files for upload into the Chemview system. The Chemview workgroup will review all data and uploaded support documents prior to final approval and publication in the public Chemview database.

#### 5.1 Chemical Identity Verification

The contractor shall review and capture information from the sanitized documents to populate the chemical identities included in either the 5(e) Consent Orders or SNUR. This identity will include the Non-Confidential Name, as well as any public CAS/Accession Number where available. The WAM shall provide written guidance on what sources and naming conventions shall be used. Due to the vast number of intended users of the system, the chemical identity requirements may vary depending on the intended report. In instances where multiple names are available for a given chemical, the contractor shall provide what information is available, and the EPA WAM will coordinate verification of the suitable names.

#### 5.2 Database Data Entry

The contractor shall use the non-confidential documents collected, and guidance provided by the WAM to enter data into the CCD Consent Order/SNUR database. The written guidance shall detail the specific fields, formatting requirements, and examples of where the information can be found for each data field. The contractor shall pose any questions to the WAM as soon as possible to allow additional guidance to be provided.

In addition, the database contains a "Comment" field designed for the contractor to enter any comments, observations, or notes they wish the WAM to review. This will allow for a formal accounting of what information was exchanged and allow for future improvements to guidance documents and/or enhancements to the database. All edits to the database shall be at the direction of the WAM.

#### 5.3 Report Generation

The contractor shall assist the EPA WAM in creation of various reports using the export functions of the CCD Consent Order/SNUR database. The contractor shall coordinate with the WAM the procedures for generation of the reports and any formatting requirements that may be needed.

### **III. Deliverables:**

Subtask 1.	The contractor shall prepare and submit the work plan in accordance with contract requirements.	
Subtask 2.	Quality Assurance Project Plan (QAPP) <ul style="list-style-type: none"><li>• Initial QAPP</li><li>• Revised QAPP(s)</li></ul>	<ul style="list-style-type: none"><li>• 10 days after WA begins</li><li>• Prior to work on environmental data activities</li></ul>
Subtask 3.	Collection of Supporting Documents (Status Update to include including identification of missing documents.)	At WAM's Request.

Subtask 4.	Formatting of Supporting Documents (Monthly status update to include reporting of progress of documents formatted, notification of any quality issues or concerns for these documents, and reporting of documents ready for WAM review.)	At WAM's Request.
Subtask 5.	CCD Consent Order/SNUR database and monthly (Monthly status update to include the progress of chemical identity verification, including notation of changes in identities and any updates made to the CCD Consent Order/SNUR database; progress on the completion of the data entry; and report generation.)	At WAM's Request.

- **EPA will approve the work plan within 45 days.**
- **A Quality Assurance Project Plan (QAPP) is required.** The contractor shall implement a quality system that meets ANSI standard E4-2014 and prepare a QAPP following OPPT/EPA guidelines. No work on the conduct of environmental data operations can begin until EPA approval of the QAPP is obtained.
- **CBI does apply.**
- **Contractor personnel shall at all times identify themselves as contractor employees, and shall not present themselves as EPA employees. Furthermore, they shall not represent views of the U.S. Government, EPA, or its employees. In addition, the contractor shall not engage in inherently governmental activities, including but not limited to actual determination of EPA policy and preparation of documents on EPA letterhead other than routine correspondences.**

#### **IV. Period of Performance:**

This Work Assignment will start with the date of the Contracting Officer's signature and extend through June 12, 2018.

#### **V. Level of Effort:**

The estimated level of effort for this work assignment is 1,600 professional hours.

#### **VI. EPA Contacts:**

##### **Primary Contracting Officer Representative**

Monica Miller  
WJC East Building, Rm 4133-D, MC 7405M  
1200 Penn. Ave, NW, Washington, DC 20460  
Phone: (202) 564-6473  
[miller.monica@epa.gov](mailto:miller.monica@epa.gov)

##### **Alternate Contracting Officer Representative**

Christopher Buckley  
WJC East Building, Rm 4121-K, MC 7405M  
1200 Penn. Ave, NW, Washington, DC 20460  
Phone: (202) 564-4817  
[Buckley.christopher@Epa.gov](mailto:Buckley.christopher@Epa.gov)

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>						Work Assignment Number 1-11				
						<input type="checkbox"/> Other <input checked="" type="checkbox"/> Amendment Number: 000001				
Contract Number EP-W-16-017			Contract Period   06/13/2017   To   06/12/2018 Base                      Option Period Number      1			Title of Work Assignment/SF Site Name				
Contractor BATTELLE MEMORIAL INSTITUTE					Specify Section and paragraph of Contract SOW Technical Support for Significant New Use Rules, C					
Purpose: <input type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input checked="" type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval					Period of Performance  From   06/13/2017   To   06/12/2018					
Comments: Amended to update statement of work for Battelle WA 1-11 Contractor shall provide workplan 30 days after receipt of work assignment.										
<input type="checkbox"/> Superfund					Accounting and Appropriations Data					<input checked="" type="checkbox"/> Non-Superfund
Note: To report additional accounting and appropriations date use EPA Form 1900-69A.										
SFO <input type="checkbox"/> (Max 2)										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:			LOE:					
06/13/2017   To   06/12/2018										
This Action:										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:					Cost/Fee			LOE:		
Cumulative Approved:					Cost/Fee			LOE:		
Work Assignment Manager Name   Martha Miller  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code:			
							Phone Number: 202-564-0295			
							FAX Number:			
Project Officer Name   Tyrone Thomas  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code:			
							Phone Number: 202-564-3121			
							FAX Number:			
Other Agency Official Name  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code:			
							Phone Number:			
							FAX Number:			
Contracting Official Name   Jody Gosnell  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code:			
							Phone Number: 202-564-4353			
							FAX Number:			

## STATEMENT OF WORK

**Contract Number:** EP-W-16-017

**Work Assignment:** 1-11 Mod #1

**Work Assignment (WA) Title:** Technical Support for Significant New Use Rules, Consent Orders, and Other New Chemical Regulatory Activities

**Work Assignment Manager (WAM)**

Tracey Klosterman, CITB, CCD, OPPT

Telephone: (202) 564-2209

E-mail: [klosterman.tracey@epa.gov](mailto:klosterman.tracey@epa.gov)

**Alternate WAM**

Yvonne Gonzalez, CITB, CCD, OPPT

Telephone: (202) 564-2912

E-mail: [gonzalez.yvonne@epa.gov](mailto:gonzalez.yvonne@epa.gov)

**Mailing Address**

U.S. EPA

1200 Pennsylvania Avenue, NW

Mail code: 7405M

Washington, DC 20460-0001

**Courier Address**

U.S. EPA

1201 Constitution Avenue, NW

Room xxxx, William Jefferson Clinton East Building

Washington, DC 20004

## BACKGROUND

The Premanufacture Notice (PMN) program is mandated by Section 5 of the Toxic Substances Control Act (TSCA). The law, enacted in 1976, gives the Environmental Protection Agency (EPA) broad authority to identify and control substances that pose a threat to human health or the environment. Anyone who plans to manufacture or import a new chemical substance for a non-exempt commercial purpose is required to provide the EPA with a PMN at least 90 days prior to the activity. EPA's New Chemicals Program (NCP), which is part of the Office of Pollution Prevention and Toxics (OPPT), is responsible for coordinating the review process of PMN submissions and identifying new substances that require regulatory action. The New Chemicals Management Branch (NCMB) in the Chemical Control Division (CCD) of OPPT is responsible for the risk management of new chemicals.

During the Agency's review period, EPA must determine whether the chemical should be regulated because it may present an unreasonable risk to human health or the environment. One method of regulation is for the EPA to enter into a Consent Order with the Company (under Section 5(e) of TSCA), which allows production of the chemical to proceed under specific restrictions. Under the Expedited Follow-up Rule effective October 10, 1989, when a 5(e) Consent Order is issued for a new chemical substance, EPA is obligated to issue a Significant New Use Rule (SNUR) within a limited period of time. Other deadlines exist for previously

issued 5(e) Orders and for new chemical substances that pass through new chemical review but are identified as non-5(e) SNUR candidates. The purpose of the Significant New Use Rule (SNUR) is to extend regulation of new chemicals beyond the PMN submitter.

In an effort to make TSCA regulatory actions more readily available to other government agencies, as well as the public, CCD will utilize information contained in the CCD Consent Order/SNUR database to create an MS Access Database to populate the Chemview system for generation of Chemview Templates. All information uploaded into the Chemview system would not contain Confidential Business Information (CBI).

The purpose of this work assignment is to provide technical support to EPA for Consent Order and SNUR rulemaking in the areas of: (1) collection, review, and formatting of supporting documents, (2) coordination of chemical identity verification, (3) data entry of information into the CCD Consent Order/SNUR database, and (4) provide technical assistance to EPA WAMs in uploading the resulting MS Access Database files into Chemview. This work assignment will involve the use of TSCA Confidential Business Information.

**PERIOD OF PERFORMANCE:** Date of issuance through June 12, 2018.

**LEVEL OF EFFORT (LOE):** The estimated LOE for this Work Assignment is being modified only to provide an additional 1,200 hours to the previous 1,600 hours and does not include any changes to the Tasks and Deliverables mentioned below.

**Task 1:                      Quality Assurance Project Plan**

This task will involve the preparation of a Quality Assurance Project Plan (QAPP). Under this task the Contractor shall prepare a QAPP to describe the quality assurance practices the Contractor will use to perform the work described in the tasks below.

**Task 2:                      Collection of Supporting Documents**

The contractor shall initiate collection of supporting and source documents including Federal Register Notices and TSCA Section 5(e) Consent Orders for PMNs identified by the WAM in written technical direction. The Contractor shall utilize all available resources, including the Documentum and CIS databases - electronic version of the files from the Confidential Business Information Center (CBIC), PMN Gold Workflow System, the CBI LAN, individual network directories, hard copy files, etc., for collection of the documents. The documents collected in this manner do not contain CBI, however, they are located in a CBI environment. In those instances, when the documents are not located in a CBI environment, they may be located on public websites including, but not limited to Regulations.gov, Pubchem, and HeinOnline.

The contractor shall create a pdf copy of all identified documents for which pdf files are not already available. If the documents are not available electronically, the Contractor shall create a scanned image of the document and convert it to a text searchable pdf format. The EPA Work Assignment Manager (WAM) shall provide guidance on naming and storage of the collected



documents. The Contractor shall notify the Work Assignment Manager (WAM) of any files which are missing.

### **Task 3:                    Formatting of Supporting Documents**

The contractor shall provide technical assistance to the WAM in formatting of supporting documents as Adobe pdfs. The WAM shall provide written guidance on the formatting requirements, including suitable metadata requirements for publication in the Chemview system. Formatted pdf documents must be text searchable to accommodate the functionality within the Chemview system.

The contractor shall track the progress of completion of these formatted documents and verify that completed reports have been posted to the correct location. For the signed 5(e) Consent Orders, the contractor shall notify the WAM of any delays in completion of the reports, and to obtain any sanitized orders that are not available. As the EPA contact, the WAM is responsible for certifying that all formatted documents are suitable for transmission to the Chemview system.

### **Task 4:                    CCD Consent Order/SNUR database**

The contractor shall use the collected 5(e) Consent Orders and Federal Register Notices for all SNURs to review and populate tables within the CCD Consent Order/SNUR database. All identified chemicals shall be entered into the system using the guidance documents provided by the WAM. Process will include the completion of a data worksheet, entry of the required data into the appropriate data tables, and QA/QC of the information for quality assurance purposes according to the approved QAPP. Any identified missing or questionable content shall be reported to the WAM. Using the information contained in the database, the contractor shall create MS Access database files for upload into the Chemview system. The Chemview workgroup will review all data and uploaded support documents prior to final approval and publication in the public Chemview database.

#### 4.1      Chemical Identity Verification

The contractor shall review and capture information from the sanitized documents to populate the chemical identities included in either the 5(e) Consent Orders or SNUR. This identity will include the Non-Confidential Name, as well as any public CAS/Accession Number where available. The WAM shall provide written guidance on what sources and naming conventions shall be used. Due to the vast number of intended users of the system, the chemical identity requirements may vary depending on the intended report. In instances where multiple names are available for a given chemical, the contractor shall provide what information is available, and the EPA WAM will coordinate verification of the suitable names.

#### 4.2      Database Data Entry

The contractor shall use the non-confidential documents collected, and guidance provided by the WAM to enter data into the CCD Consent Order/SNUR database. The written guidance shall detail the specific fields, formatting requirements, and examples of where the information can be

found for each data field. The contractor shall pose any questions to the WAM as soon as possible to allow additional guidance to be provided.

In addition, the database contains a “Comment” field designed for the contractor to enter any comments, observations, or notes they wish the WAM to review. This will allow for a formal accounting of what information was exchanged and allow for future improvements to guidance documents and/or enhancements to the database. All edits to the database shall be at the direction of the WAM.

### 4.3 Report Generation

The contractor shall assist the EPA WAM in creation of various reports using the export functions of the CCD Consent Order/SNUR database. The contractor shall coordinate with the WAM the procedures for generation of the reports and any formatting requirements that may be needed.

**DELIVERABLES:** All deliverables shall be submitted to the WAM electronically (Adobe pdf).

- Task 1**      The Contractor shall submit a QAPP within 2 weeks of approval of the work plan.
- Task 2**      The contractor shall submit to the EPA WAM written updates on the status of completion of the tasks on a monthly basis. The update should include identification of any missing documents.
- Task 3**      The contractor shall submit to the WAM written updates on the completion of the subtasks in this task on a monthly basis. The update should include reporting of progress of documents formatted, notification of any quality issues or concerns for these documents, and reporting of documents ready for WAM review.
- Task 4**      The contractor shall submit to the WAM written updates on completion of the subtasks in this task on a monthly basis. The update should include reporting on the progress of chemical identity verification, including notation of changes in identities and any updates made to the CCD Consent Order/SNUR database. The contractor shall report progress on the completion of the data entry.

### **ADDITIONAL INFORMATION**

- Contractor personnel shall at all times identify themselves as contractor employees, and shall not present themselves as EPA employees. Furthermore, they shall not represent views of the U.S. Government, EPA, or its employees. In addition, the contractor shall not engage in inherently governmental activities, including but not limited to actual determination of EPA policy and preparation of documents on EPA letterhead other than routine correspondences.

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>						Work Assignment Number 1-12				
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:				
Contract Number EP-W-16-017			Contract Period   06/13/2016   To   06/12/2018 Base                      Option Period Number      1			Title of Work Assignment/SF Site Name CBI LAN Reviews				
Contractor BATTELLE MEMORIAL INSTITUTE					Specify Section and paragraph of Contract SOW					
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance  From   06/13/2017   To   06/12/2018				
Comments: Initiate work assignment. The Contractor shall provide a work plan within 30 days of receipt of the work assignment										
<input type="checkbox"/> Superfund                      Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
SFO <input type="checkbox"/> Note: To report additional accounting and appropriations date use EPA Form 1900-69A. (Max 2)										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:                      Cost/Fee:                      LOE: 0 06/13/2016   To   06/12/2018										
This Action:						0				
Total:						0				
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:                      Cost/Fee                      LOE:										
Cumulative Approved:                      Cost/Fee                      LOE:										
Work Assignment Manager Name    Skyler Dobert  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 202-564-3159 FAX Number:			
Project Officer Name    Tyrone Thomas  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 202-564-3121 FAX Number:			
Other Agency Official Name  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: FAX Number:			
Contracting Official Name    Jody Gosnell  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 202-564-4353 FAX Number:			

## **Statement of Work**

**Contract Number:** EP-W-16-017

**Work Assignment Number:** 1-12

**Title:** Support for CBI Reviews as Required by TSCA section 14(g)

### **Purpose:**

The Purpose of this Work Assignment is to assemble and extract selected data from TSCA submissions containing information claimed as CBI, and provide a written analysis sufficient to allow for the program office consideration of the validity of the identified CBI claims and then the generation of a recommendation to meet the requirements for a final determination as required under TSCA section 14(g) data related to submitted with new chemical notices and input the information into appropriate databases. The level of detail will vary depending on the type of filing subject to review, and relevant statutory, regulatory and policy considerations.

### **I. Background:**

The Office of Pollution Prevention and Toxics (OPPT) is charged under the Toxic Substances Control Act (TSCA) with reviewing confidential business information (CBI) claims and making recommendations for final determinations concerning the potential validity of these claims. TSCA section 14(g). Because of the statutory mandate that these reviews occur within ninety days of receipt of the documents, identification of the claims, initial data entry, data assembly/extraction, and creation of useful and related information products must occur in a timely fashion in order for it to be used in the statutorily mandated process. These documents will be TSCA submissions directed to the Agency under all provisions of TSCA, as well as follow-up materials, including amendments and substantiations or responses to requests for comments. To address this broad need, the EPA will rely on contractor support to assist in the extraction, summary, and initial analysis/assessment of the data to facilitate the Agency CBI review and determination process.

### **II. Scope of Work:**

#### **Subtask 1. Work Plan and Task Management**

The Contractor shall submit a work plan that describes tasks, the planned approach, schedule, estimated direct labor hours by labor level, and associated budget. The Contractor may request a meeting (via conference call) with the WAM to seek clarification or to answer any questions prior to the submission of the above work plan.

Upon approval of the work plan, the Contractor shall maintain at least biweekly communication with the WAM regarding the status of the work assignment. Additional points of contact under this work assignment are noted below in VI EPA contacts.

#### **Subtask 2. Quality Assurance Project Plan (QAPP)**

A Quality Assurance Project Plan (QAPP) is required. A Quality Assurance Project Plan documents the planning, implementation, and assessment procedures for a particular project, as well as any specific quality assurance and quality control activities. It integrates all the technical and quality aspects of the project in order to provide a "blueprint" for obtaining the type and quality of environmental data and information needed for a specific decision or use. All work performed or funded by EPA that involves the acquisition of environmental data must have an

approved Quality Assurance Project Plan. Details for developing a QAPP can be found at: <https://www.epa.gov/sites/production/files/2015-06/documents/g5-final.pdf> and the Contractor shall be responsible for the development and revisions to the QAPP.

### **Subtask 3. TSCA CBI reviews**

The Contractor shall review all documents subject to the TSCA 14(g) CBI review requirements, and extract from each file the data and studies pertinent to the assessment of the CBI claims. These will largely be extracted from substantiations as authorized under the regulations and policies provided by the information submitters.

- a. The Contractor shall cause the data to be abstracted and entered into the designated database or spread sheet or template.
- b. The Contractor shall also summarize the basis for the submitters' claims of confidentiality, providing specific sources for the summary points (e.g. loss of competitive advantage, Response 3, secret that substance is in commerce, Response 6 etc.) The Contractor shall provide a written analysis sufficient to allow for the Program Office consideration of the validity of the identified CBI claims.
- c. The Contractor shall be called to engage in literature searches related to the reviews.
- d. The activities and the generated work-products of the Contractor shall be assembled into formats and template of the Program Office's design.
- e. The Contractor shall participate in meetings and trainings related to TSCA CBI reviews and incorporate EPA procedural updates in to the workflow as appropriate.

### **Subtask 4. Confidentiality**

The majority of the material related to this activity is claimed by the submitters as TSCA Confidential Business Information, TSCA CBI clearance and adherence to TSCA CBI procedures are required through the duration of the WA.

### **III. Deliverables:**

Subtask 1.	The contractor shall prepare and submit the work plan in accordance with contract requirements.  Upon approval of the work plan, the Contractor shall maintain at least biweekly communication with the WAM.	<ul style="list-style-type: none"> <li>• At the start of the WA.</li> <li>• Bi-weekly status meetings with WAM.</li> </ul>
Subtask 2.	Quality Assurance Project Plan (QAPP) <ul style="list-style-type: none"> <li>• Initial QAPP</li> <li>• Revised QAPP(s)</li> </ul>	<ul style="list-style-type: none"> <li>• 10 days after WA begins</li> <li>• Prior to work on environmental data activities</li> </ul>
Subtask 3.	TSCA CBI reviews	At WAM's Request.

Subtask 4.	The Contractor shall gain and maintain TSCA CBI clearance through the duration of the work assignment	At the start of the WA.
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- **EPA will approve the work plan within 45 days.**

**A Quality Assurance Project Plan (QAPP) is required.** The contractor shall implement a quality system that meets ANSI standard E4-2014 and prepare a quality assurance project plan (QAPP) following OPPT/EPA guideline. No work on the conduct of environmental data operations can begin until EPA approval of the QAPP is obtained.

- **A work plan is required.**
- **CBI does apply.**

**IV. Period of Performance:** the WA will begin on the date of the Contracting Officers Signature and end on 6/12/2018

**V. Estimated Level of Effort:** 1060 professional hours.

**VI. EPA Contacts:**

**Primary Contracting Officer Representative**

Skyler Dobert  
WJC East Building, Rm 4218-C, MC 7408M  
1200 Penn. Ave, NW, Washington, DC 20460  
Phone: (202) 564-3159  
[Dobert.skyler@epa.gov](mailto:Dobert.skyler@epa.gov)

**Alternate Contracting Officer Representative**

Not yet assigned

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>						Work Assignment Number 1-13				
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:				
Contract Number EP-W-16-017			Contract Period   06/13/2016   To   06/12/2021 Base                      Option Period Number      1			Title of Work Assignment/SF Site Name OSCP EDSP Support				
Contractor Battelle Memorial Institute					Specify Section and paragraph of Contract SOW					
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance  From   06/13/2017   To   06/12/2018				
Comments: Initiating a work assignment on EP-W-16-017. The contractor shall provide a work plan within 30 days of receipt of this work assignment.										
<input type="checkbox"/> Superfund                      Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
SFO <input type="checkbox"/> Note: To report additional accounting and appropriations date use EPA Form 1900-69A. (Max 2)										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:				LOE: 0				
06/13/2016 To 06/12/2021										
This Action:						0				
Total:						0				
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:				Cost/Fee			LOE:			
Cumulative Approved:				Cost/Fee			LOE:			
Work Assignment Manager Name    Sharlene Matten  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 202-564-0130 FAX Number:			
Project Officer Name    Tyrone Thomas  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 202-564-3121 FAX Number:			
Other Agency Official Name    Keith Westry  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 202-564-9863 FAX Number:			
Contracting Official Name    Jody Gosnell  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 202-564-4353 FAX Number:			

Contract Number: EP-W-16-017

Work Assignment Number: 1-13

**Title:** Office of Science, Coordination and Policy, Endocrine Disruptor Screening Program Support: Records Management, Statistical and Data Analysis, Meeting Assistance, and Special Projects

**Purpose:**

This work assignment, *Office of Science, Coordination and Policy, Endocrine Disruptor Screening Program Support: Records Management, Statistical and Data Analysis, Meeting Assistance, and Special Projects*, shall provide support to the Endocrine Disruptor Screening Program (EDSP). No work performed under previous task orders or work assignments will be duplicated under Work Assignment 1-13, EP-W-16-017.

**I. Background**

This work assignment, *Office of Science, Coordination and Policy, Endocrine Disruptor Screening Program Support: Records Management, Statistical and Data Analysis, Meeting Assistance, and Special Projects*, will provide support for four (4) specific areas:

1. Records management
2. Data analysis and statistical support
3. Meeting support
4. Special projects.

The Endocrine Disruptor Screening Program (EDSP) was established in 1998 under authorities contained in the 1996 Food Quality Protection Act (FQPA) and the 1996 Safe Drinking Water Act (SDWA) amendments. As mandated by these statutes, the EDSP develops a screening program to determine whether certain substances may have endocrine activity in humans and wildlife. The US EPA has developed a two tiered approach for screening chemicals and pesticides. The Tier 1 battery is used to identify substances that have potential to interact with the estrogen, androgen or thyroid hormone pathways. The Tier 2 tests identify and establish dose response information for adverse effects for substances identified in the Tier 1 screening. Beginning in 2015, the EDSP is incorporating ToxCast high throughput screening data and computational models in the prioritization and screening of a chemical's potential to interact with the endocrine system in humans and wildlife for a portion of the Tier 1 battery. This approach will allow nearly 20 times the current number of screenings to be performed while nearly eliminating animal testing, allowing the program to meet its goals with a relatively level budget.

The EPA's EDSP is continuing the development and validation of alternative testing methodologies (i.e., high throughput assays and computational tools) to prioritize and screen chemicals based on potential endocrine bioactivity and exposure--in particular, the estrogen, androgen, or thyroid hormone pathways in humans and wildlife. This increased use of alternative testing methodologies will improve the output of screening results, allowing for greater coverage of the endocrine system.

Work Assignment 1-13 of EPA Contract No. EP-W-16-017 will continue records management work conducted by Battelle on Task Order 19 of EPA Contract No. EP-W-11-063 (Subtask 3), and statistical support and data analysis of the studies conducted by Battelle on Task Orders 14, 17, and 19 of EPA Contract No. EP-W-11-063 and conducted by RTI on Task Orders 12 and 13 of EPA Contract No. EP-W-11-065 (Subtask 4). No work performed under these earlier task orders will be duplicated under Work Assignment 1-13. Work Assignment 1-13 also includes support for meetings (Subtask 5) and special projects (Subtask 6).



## **II. Statement of Work**

### **Subtask 1. Work Plan and Task Management**

1. The contractor shall prepare and submit a work plan in accordance with the requirements of this contract. Work under this subtask will include participating in conference calls, preparing monthly progress reports, and other task management activities.
2. The contractor shall immediately notify the EPA WA COR if there are any problems that affect the production and delivery of deliverables.
3. The contractor shall provide all deliverables in an electronic format specified by the EPA WA COR (e.g., Word, Excel, Access, HTML) via electronic mail. Unless otherwise specified by the EPA WA COR, Battelle shall provide a secure method for internet transfer of large files. All Deliverables for WA 1-13 are the property of EPA.
4. The contractor shall format any deliverables intended for posting on an EPA public website to comply with Section 508.

### **Subtask 2. Quality Assurance Project Plan (QAPP)**

The contractor shall create a Quality Assurance Project Plan (QAPP) that documents the planning, implementation, and assessment procedures for subtasks 4 and 6 in this SOW, as well as any specific quality assurance and quality control activities. The QAPP integrates all of the technical and quality aspects of the project in order to provide a blueprint for obtaining the type and quality of environmental data and information needed for a specific decision or use. All work performed or funded by EPA that involves the acquisition of environmental data must have an approved QAPP. Details for developing a QAPP can be found at: <https://www.epa.gov/sites/production/files/2015-06/documents/g5-final.pdf> and the contractor shall be responsible for the development of, and any revisions to, the QAPP. Revisions to the QAPP must be made prior to beginning environmental data activities.

### **Subtask 3. Records Management**

The contract shall provide EPA with technical assistance on activities related to records management.

1. The contractor shall assist EPA in managing records, in all media, according to the disposition instructions in EPA record management schedules, including but not limited to:
  - EPA Record Schedule 1035 - Environmental Records
  - EPA Record Schedule 1004 - Acquisitions and Contracts
  - EPA Records Schedule 1024 - Federal Advisory Committee Records
2. The contractor shall provide support for:
  - Organizing and indexing records
  - Packing and labeling boxes containing records for transfer to a Federal Records Center or as a direct offer to the National Archives and Records Administration.
  - Preparing individual box lists
  - Preparing destruction lists for records that will be destroyed and destroying them
  - E-record management
3. The contractor shall provide the WA COR with:
  - Draft and final indices of records (in all media)

- Draft and final box lists
  - Organized, packed, and labelled records boxes for transfer to FRC or NARA
  - Draft and final records destruction forms.
4. The contractor shall conduct work with paper records at EPA William Jefferson Clinton East, Office of Science and Coordination Policy, Washington D.C., unless otherwise dictated by the EPA WA COR.
  5. The contractor shall have one technical meeting per week with Battelle and/or its subcontractor.

#### **Subtask 4: Statistical Support and Data Analysis**

The contractor shall provide EPA with technical assistance in data and biostatistical analysis, particularly data from toxicological/toxicokinetic studies. EPA may order work that requires a short turn-around time. Battelle shall use, to the extent possible, open source tools, e.g., programs in R.

The contractor shall provide support for:

1. Data and statistical analysis, e.g., compiling and evaluating *in vitro* and *in vivo* data from multiple sources, preparing or revising reports, statistical support and data analysis for publication, preparing data evaluation records using EPA study profile templates for the EDSP, etc.;
2. Data management related to specific data/statistical analyses.

The contractor shall prepare draft and final analyses/reports/DERs, etc. per the WA COR's instructions.

Examples include:

1. Development of EPA Data Evaluation Records from EPA-sponsored laboratory studies including supporting statistical analysis, as needed.
2. Statistical analysis of EPA data either for an individual study or multiple studies
3. Meta-analysis of collected data from EPA *in vitro/in vivo* studies
4. RSCABS of EPA histopathology data
5. Data and statistical analysis of EPA toxicokinetics data
6. Cross-species analyses
7. Analysis of *in vitro* toxicokinetics data in trout, rat, and human.

#### **Subtask 5: Meeting Support**

The contractor shall provide EPA with meeting support, e.g., EPA meetings/workshops which are open to specific invitees or open to public.

For example, Battelle shall assist EPA in the following areas:

- Logistical support, e.g., managing a webinar, managing audio/visual equipment
- Meeting facilitation
- Development of meeting materials
- Posting materials to EPA websites
- Note-taking/transcription at a meeting
- Summary reports from the meeting
- Meeting invitations and tracking responses

## Subtask 6: Special Projects

The contractor shall provide EPA with assistance on activities including, but not limited to, conducting technical studies on chemicals that are from the EDSP Universe and the TSCA work plan.

Studies may include the evaluation of new and emerging technologies to measure, detect, or reduce exposure to toxic substances.

**Example - Investigation of volatility and solubility.** EPA has designed a Cell Culture Exposure System for *in vitro* testing of volatile chemicals. The contractor shall build the device to test volatile chemicals from the EDSP Universe and the TSCA Work Plan.

The contractor shall prepare draft and final analyses/reports etc. per the WA COR's instructions.

## III. Deliverables

The contractor shall provide deliverables as shown in Table 1.

Table 1. Deliverables and Schedule

Tasks	Deliverables	Due Dates
Subtask 1	Work plan and task management The contractor shall prepare and submit the work plan in accordance with contract requirements.	
Subtask 2	Quality Assurance Project Plan (QAPP) 1. Draft QAPP 2. Final QAPP	1. Draft: 10 days after WA begins 2. Prior to work on environmental data activities
Subtask 3	Records Management	At Work Assignment COR's request.
Subtask 4	Data Analysis and Statistical Support	At Work Assignment COR's request.
Subtask 5	Meeting Support	At Work Assignment COR's request.
Subtask 6	Special Projects	At Work Assignment COR's request.

- 1. EPA will approve the work plan within 30 days.**
- 2. A Quality Assurance Project Plan (QAPP) is required (Subtasks 4 and 6).** The contractor shall implement a quality system that meets ANSI standard E4-2014 and prepare a QAPP following OPPT/EPA guidelines. No work on the conduct of environmental data operations can begin until EPA approval of the QAPP is obtained.
- 3. CBI does not apply.**
- 4. Contractor personnel shall at all times identify themselves as contractor employees, and shall not present themselves as EPA employees. Furthermore, they shall not represent view of the U.S. Government, EPA, or its employees. In addition, the contractor shall not engage in inherently**

**governmental activities, including, but not limited to actual determination of EPA policy and preparation of documents on EPA letterhead other than routine correspondences.**

#### **IV. Period of Performance**

This Work Assignment will start with the date of the Contracting Officer's signature and extend through June 12, 2018.

#### **V. Estimated Level of Effort: 1,000 professional hours.**

#### **VI. EPA Contacts:**

##### **Primary Contracting Officer Representative**

Sharlene R. Matten, Ph.D.

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1200 Penn. Ave, NW, Washington, DC 20460

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##### **Alternate Contracting Officer Representative**

Kristan Markey

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Phone: (202) 564-8716

[markey.kristan@epa.gov](mailto:markey.kristan@epa.gov)

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>						Work Assignment Number 1-13				
						<input type="checkbox"/> Other <input checked="" type="checkbox"/> Amendment Number: 000001				
Contract Number EP-W-16-017			Contract Period   06/13/2018   To   06/12/2019 Base <input checked="" type="checkbox"/> Option Period Number			Title of Work Assignment/SF Site Name OSCP EDSP Rec Man, Data Analy				
Contractor BATTELLE MEMORIAL INSTITUTE					Specify Section and paragraph of Contract SOW					
Purpose: <input type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input checked="" type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance  From   06/13/2017   To   06/12/2018				
Comments: The purpose of this amendment is to add 600 work hours to work assignment WA 1-13. The focus of the additional hours will be to complete work under Subtask 3, Records Management and Subtask 5, Meeting Support. Subtask 6 (Special Projects) has been changed to an optional subtask. Finally, the alternate										
<input type="checkbox"/> Superfund    Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
SFO <input type="checkbox"/> Note: To report additional accounting and appropriations date use EPA Form 1900-69A. (Max 2)										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:				LOE:				
06/13/2018   To   06/12/2019										
This Action:										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:					Cost/Fee			LOE:		
Cumulative Approved:					Cost/Fee			LOE:		
Work Assignment Manager Name   Sharlene Matten  <div style="display: flex; justify-content: space-between; border-top: 1px solid black; margin-top: 10px;"> <span>(Signature)</span> <span>(Date)</span> </div>							Branch/Mail Code:			
							Phone Number: 202-564-0130			
							FAX Number:			
Project Officer Name   Tyrone Thomas  <div style="display: flex; justify-content: space-between; border-top: 1px solid black; margin-top: 10px;"> <span>(Signature)</span> <span>(Date)</span> </div>							Branch/Mail Code:			
							Phone Number: 202-564-3121			
							FAX Number:			
Other Agency Official Name  <div style="display: flex; justify-content: space-between; border-top: 1px solid black; margin-top: 10px;"> <span>(Signature)</span> <span>(Date)</span> </div>							Branch/Mail Code:			
							Phone Number:			
							FAX Number:			
Contracting Official Name   Keith Westry  <div style="display: flex; justify-content: space-between; border-top: 1px solid black; margin-top: 10px;"> <span>(Signature)</span> <span>(Date)</span> </div>							Branch/Mail Code:			
							Phone Number: 202-564-9863			
							FAX Number:			

Contract Number: EP-W-16-017  
Addendum to Work Assignment Number 1-13

Title: Office of Science, Coordination and Policy, Endocrine Disruptor Screening Program Support: Records Management, Statistical and Data Analysis, Meeting Assistance, and Special Projects

**Purpose:**

**The purpose of this addendum is to add 600 work hours to work assignment WA 1-13. The focus of the additional hours will be to complete work under Subtask 3, Records Management and Subtask 5, Meeting Support. Subtask 6 (Special Projects) has been changed to an optional subtask. Finally, the alternate Work Assignment COR has been changed from Kristan Markey to Scott Lynn.**

This work assignment, *Office of Science, Coordination and Policy, Endocrine Disruptor Screening Program Support: Records Management, Statistical and Data Analysis, Meeting Assistance, and Special Projects*, shall provide support to the Endocrine Disruptor Screening Program (EDSP). No work performed under previous task orders or work assignments will be duplicated under Work Assignment 1-13, EP-W-16-017.

## **I. Background**

This work assignment, *Office of Science, Coordination and Policy, Endocrine Disruptor Screening Program Support: Records Management, Statistical and Data Analysis, Meeting Assistance, and Special Projects*, will provide support for four (4) specific areas:

1. Records management
2. Data analysis and statistical support
3. Meeting support
4. Special projects.

The Endocrine Disruptor Screening Program (EDSP) was established in 1998 under authorities contained in the 1996 Food Quality Protection Act (FQPA) and the 1996 Safe Drinking Water Act (SDWA) amendments. As mandated by these statutes, the EDSP develops a screening program to determine whether certain substances may have endocrine activity in humans and wildlife. The US EPA has developed a two-tiered approach for screening chemicals and pesticides. The Tier 1 battery is used to identify substances that have potential to interact with the estrogen, androgen or thyroid hormone pathways. The Tier 2 tests identify and establish dose response information for adverse effects for substances identified in the Tier 1 screening. Beginning in 2015, the EDSP is incorporating ToxCast high throughput screening data and computational models in the prioritization and screening of a chemical's potential to interact with the endocrine system in humans and wildlife for a portion of the Tier 1 battery. This approach will allow nearly 20 times the current number of screenings to be performed while nearly eliminating animal testing, allowing the program to meet its goals with a relatively level budget.

The EPA's EDSP is continuing the development and validation of alternative testing methodologies (i.e., high throughput assays and computational tools) to prioritize and screen chemicals based on potential endocrine bioactivity and exposure--in particular, the estrogen, androgen, or thyroid hormone pathways in humans and wildlife. This increased use of alternative testing methodologies will improve the output of screening results, allowing for greater coverage of the endocrine system.

Work Assignment 1-13 of EPA Contract No. EP-W-16-017 will continue records management work conducted by Battelle on Task Order 19 of EPA Contract No. EP-W-11-063 (Subtask 3), and statistical support and data

analysis of the studies conducted by Battelle on Task Orders 14, 17, and 19 of EPA Contract No. EP-W-11-063 and conducted by RTI on Task Orders 12 and 13 of EPA Contract No. EP-W-11-065 (Subtask 4). No work performed under these earlier task orders will be duplicated under Work Assignment 1-13. Work Assignment 1-13 also includes support for meetings (Subtask 5) and special projects (Subtask 6).

## **II. Statement of Work**

### **Subtask 1. Work Plan and Task Management**

1. The contractor shall prepare and submit a work plan in accordance with the requirements of this contract. Work under this subtask will include participating in conference calls, preparing monthly progress reports, and other task management activities.
2. The contractor shall immediately notify the EPA WA COR if there are any problems that affect the production and delivery of deliverables.
3. The contractor shall provide all deliverables in an electronic format specified by the EPA WA COR (e.g., Word, Excel, Access, HTML) via electronic mail. Unless otherwise specified by the EPA WA COR, Battelle shall provide a secure method for internet transfer of large files. All Deliverables for WA 1-13 are the property of EPA.
4. The contractor shall format any deliverables intended for posting on an EPA public website to comply with Section 508.

### **Subtask 2. Quality Assurance Project Plan (QAPP)**

The contractor shall create a Quality Assurance Project Plan (QAPP) that documents the planning, implementation, and assessment procedures for subtasks 4 and 6 in this SOW, as well as any specific quality assurance and quality control activities. The QAPP integrates all of the technical and quality aspects of the project in order to provide a blueprint for obtaining the type and quality of environmental data and information needed for a specific decision or use. All work performed or funded by EPA that involves the acquisition of environmental data must have an approved QAPP. Details for developing a QAPP can be found at: <https://www.epa.gov/sites/production/files/2015-06/documents/g5-final.pdf> and the contractor shall be responsible for the development of, and any revisions to, the QAPP. Revisions to the QAPP must be made prior to beginning environmental data activities.

### **Subtask 3. Records Management**

The contract shall provide EPA with technical assistance on activities related to records management.

1. The contractor shall assist EPA in managing records, in all media, according to the disposition instructions in EPA record management schedules, including but not limited to:
  - EPA Record Schedule 1035 - Environmental Records
  - EPA Record Schedule 1004 - Acquisitions and Contracts
  - EPA Records Schedule 1024 - Federal Advisory Committee Records
2. The contractor shall provide support for:
  - Organizing and indexing records
  - Packing and labeling boxes containing records for transfer to a Federal Records Center or as a direct offer to the National Archives and Records Administration.
  - Preparing individual box lists

- Preparing destruction lists for records that will be destroyed and destroying them
  - E-record management
3. The contractor shall provide the WA COR with:
    - Draft and final indices of records (in all media)
    - Draft and final box lists
    - Organized, packed, and labelled records boxes for transfer to FRC or NARA
    - Draft and final records destruction forms.
  4. The contractor shall conduct work with paper records at EPA William Jefferson Clinton East, Office of Science and Coordination Policy, Washington D.C., unless otherwise dictated by the EPA WA COR.
  5. The contractor shall have one technical meeting per week with Battelle and/or its subcontractor.

#### **Subtask 4: Statistical Support and Data Analysis**

The contractor shall provide EPA with technical assistance in data and biostatistical analysis, particularly data from toxicological/toxicokinetic studies. EPA may order work that requires a short turn-around time. Battelle shall use, to the extent possible, open source tools, e.g., programs in R.

The contractor shall provide support for:

1. Data and statistical analysis, *e.g.*, compiling and evaluating *in vitro* and *in vivo* data from multiple sources, preparing or revising reports, statistical support and data analysis for publication, preparing data evaluation records using EPA study profile templates for the EDSP, *etc.*;
2. Data management related to specific data/statistical analyses.

The contractor shall prepare draft and final analyses/reports/DERs, etc. per the WA COR's instructions.

Examples include:

1. Development of EPA Data Evaluation Records from EPA-sponsored laboratory studies including supporting statistical analysis, as needed.
2. Statistical analysis of EPA data either for an individual study or multiple studies
3. Meta-analysis of collected data from EPA *in vitro/in vivo* studies
4. RSCABS of EPA histopathology data
5. Data and statistical analysis of EPA toxicokinetics data
6. Cross-species analyses
7. Analysis of *in vitro* toxicokinetics data in trout, rat, and human.

#### **Subtask 5: Meeting Support**

The contractor shall provide EPA with meeting support, *e.g.*, EPA meetings/workshops which are open to specific invitees or open to public. The primary focus of this subtask will be on providing support for note-taking, transcription, and summary reports of EPA meetings.

For example, Battelle may also assist EPA in the following areas:

- Logistical support, *e.g.*, managing a webinar, managing audio/visual equipment
- Meeting invitations and tracking responses
- Development of meeting materials



### Subtask 6 (Optional): Special Projects

The contractor shall provide EPA with assistance on activities including, but not limited to, conducting technical studies on chemicals that are from the EDSP Universe and the TSCA work plan.

Studies may include the evaluation of new and emerging technologies to measure, detect, or reduce exposure to toxic substances.

**Example - Investigation of volatility and solubility.** EPA has designed a Cell Culture Exposure System for *in vitro* testing of volatile chemicals. The contractor shall build the device to test volatile chemicals from the EDSP Universe and the TSCA Work Plan.

The contractor shall prepare draft and final analyses/reports etc. per the WA COR's instructions.

### III. Deliverables

The contractor shall provide deliverables as shown in Table 1.

Table 1. Deliverables and Schedule

SubtaskNo.	Deliverable Title/Brief Description	Original Due Date	Revised Due Date	Percent Complete (as of 5/1/2018)
1	Technical and Financial Work Plan (MAY NEED TO ADD HOURS)	10/25/17	11/20/17	100
2	Draft QAPP	10/10/17	11/13/17	100
2	Final QAPP	--	1/15/18	100
3	Records Management deliverables (NEED TO ADD HOURS)	TBD in technical direction	Weekly updates starting 12/1/17	75
4	Data Analysis and Statistical Support deliverables	TBD in technical direction	1. 2/21/18	33
5	Meeting Support (NEED TO ADD HOURS)	TBD in technical direction	As required in technical directive	50
6	Special Projects (Optional) [No work requested during this option period ending June 12, 2018.]	TBD in technical direction	As required in technical directive	0

- 1. EPA will approve the work plan within 30 days.**
- 2. A Quality Assurance Project Plan (QAPP) is required (Subtasks 4 and 6).** The contractor shall implement a quality system that meets ANSI standard E4-2014 and prepare a QAPP following OPPT/EPA guidelines. No work on the conduct of environmental data operations can begin until EPA approval of the QAPP is obtained.
- 3. CBI does not apply.**
- 4. Contractor personnel shall at all times identify themselves as contractor employees, and shall not present themselves as EPA employees. Furthermore, they shall not represent view of the U.S. Government, EPA, or its employees. In addition, the contractor shall not engage in inherently**

**governmental activities, including, but not limited to actual determination of EPA policy and preparation of documents on EPA letterhead other than routine correspondences.**

#### **IV. Period of Performance**

This Work Assignment will start with the date of the Contracting Officer's signature and extend through June 12, 2018.

- V. **Amended Estimated Level of Effort:** Additional 600 professional hours. Total estimated level of effort 1700 professional hours.

#### **VI. EPA Contacts:**

**Primary Contracting Officer Representative**

Sharlene R. Matten, Ph.D.

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[matten.sharlene@epa.gov](mailto:matten.sharlene@epa.gov)

**Alternate Contracting Officer Representative**

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1200 Penn. Ave, NW, Washington, DC 20460

Phone: (202) 564-2631

[lynn.scott@epa.gov](mailto:lynn.scott@epa.gov)

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>						Work Assignment Number 1-14				
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:				
Contract Number EP-W-16-017			Contract Period   06/13/2016   To   06/12/2018 Base <input checked="" type="checkbox"/> Option Period Number			Title of Work Assignment/SF Site Name OSCP Alternative Testing				
Contractor BATTELLE MEMORIAL INSTITUTE					Specify Section and paragraph of Contract SOW					
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance  From   06/13/2017   To   06/12/2018				
Comments: Initiating a work assignment on EP-W-16-017. The contractor shall provide a work plan within 30 days of receipt of this work assignment.										
<input type="checkbox"/> Superfund                      Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
SFO <input type="checkbox"/> Note: To report additional accounting and appropriations date use EPA Form 1900-69A. (Max 2)										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:                      Cost/Fee:                      LOE: 06/13/2016   To   06/12/2018										
This Action:  										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:                      Cost/Fee                      LOE:										
Cumulative Approved:                      Cost/Fee                      LOE:										
Work Assignment Manager Name    Kristan Markey  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 202 564 8716 FAX Number:			
Project Officer Name    Tyrone Thomas  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 202-564-3121 FAX Number:			
Other Agency Official Name  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: FAX Number:			
Contracting Official Name    Jody Gosnell  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 202-564-4353 FAX Number:			

Contract Number: EP-W-16-017

Work Assignment Number: 1-14

**Title: EPA Office of Science and Coordination Policy, Alternative Testing Strategy, Data Science, and Systematic Review Support**

**Purpose:**

This work assignment, *EPA Office of Science and Coordination Policy, Alternative Testing Strategy, Data Science, and Systematic Review Support*, will provide technical support to the Office of Science Coordination and Policy (OSCP) in EPA's Office of Chemical Safety & Pollution Prevention (OCSPP) including the development of the EPA Office of Pollution Prevention and Toxics (OPPT) Alternative Testing Strategy, performance-validation of high throughput (HT) assays, computational models for the estrogen, androgen, and thyroid pathways and cross-species validation studies; and development and prioritization of chemicals in EPA's Endocrine Disruptor Screening Program. No work performed under previous task orders or work assignments will be duplicated under Work Assignment 1-14, EP-W-16-017.

**I. Background**

This work assignment will provide technical support in three specific areas:

1. Support the development of the EPA Office of Pollution Prevention and Toxics (OPPT) Alternative Testing Strategy under Section 4 of the Frank R. Lautenberg Chemical Safety for the 21st Century Act via development of an inventory of testing requests and existing data and analysis of this inventory;
2. Support EDSP linear and pathway-based systematic literature reviews to support the performance-based validation of high throughput (HT) assays, computational models for the estrogen, androgen, and thyroid pathways and cross-species validation studies
3. Support collecting, prioritizing, and analyzing in vitro and in vivo data for display on the EPA Comptox dashboard via systematic review (SR) and high-throughput assays (in vitro only)

The Office of Science and Coordination Policy manages EPA's Endocrine Disruptor Screening Program (EDSP). The EDSP was established in 1998 under authorities contained in the 1996 Food Quality Protection Act (FQPA) and the 1996 Safe Drinking Water Act (SDWA) amendments. As mandated by these statutes, the EDSP develops a screening program to determine whether certain substances may have endocrine activity in humans and wildlife. The US EPA has developed a two tiered approach for screening chemicals and pesticides. The Tier 1 battery is used to identify substances that have potential to interact with the estrogen, androgen or thyroid hormone pathways. The Tier 2 tests identify and establish dose response information for adverse effects for substances identified in the Tier 1 screening. Beginning in 2015, the EDSP is incorporating ToxCast high throughput screening data and computational models in the prioritization and screening of a chemical's potential to interact with the endocrine system in humans and wildlife for a portion of the Tier 1 battery. This approach will allow nearly 20 times the current number of screenings to be performed while nearly eliminating animal testing, allowing the program to meet its goals with a relatively level budget.

The EPA's EDSP is continuing the development and validation of alternative testing methodologies (i.e., high throughput assays and computational tools) to prioritize and screen chemicals based on potential endocrine bioactivity and exposure--in particular, the estrogen, androgen, or thyroid hormone pathways in humans and wildlife. This increased use of alternative testing methodologies will improve the output of screening results allowing for greater coverage of the endocrine system.

## **I. Statement of Work**

### **Subtask 1. Work Plan and Task Management**

1. The contractor shall prepare and submit a work plan in accordance with the requirements of this contract. Work under this subtask will include participating in conference calls, preparing monthly progress reports, and other task management activities.
2. The contractor shall immediately notify the EPA WA COR if there are any problems that affect the production and delivery of deliverables.
3. The contractor shall provide all deliverables in an electronic format specified by the EPA WA COR (e.g., Word, Excel, Access, HTML) via electronic mail. Unless otherwise specified by the EPA WA COR, Battelle shall provide a secure method for internet transfer of large files.
4. All Deliverables for WA 1-14 are the property of EPA (including any scripts or computer code developed accomplish analyses).
5. The contractor shall format any deliverables intended for posting on an EPA public website to comply with Section 508.

### **Subtask 2. Quality Assurance Project Plan (QAPP)**

The contractor shall create a Quality Assurance Project Plan (QAPP) that documents the planning, implementation, and assessment procedures for subtasks 3, 4, and 5 in this SOW, as well as any specific quality assurance and quality control activities. The QAPP integrates all of the technical and quality aspects of the project in order to provide a blueprint for obtaining the type and quality of environmental data and information needed for a specific decision or use. All work performed or funded by EPA that involves the acquisition of environmental data must have an approved QAPP. Details for developing a QAPP can be found at: <https://www.epa.gov/sites/production/files/2015-06/documents/g5-final.pdf> and the contractor shall be responsible for the development of, and any revisions to, the QAPP. Revisions to the QAPP must be made prior to beginning environmental data activities.

### **Subtask 3. Development of the EPA Office of Pollution Prevention and Toxics (OPPT) Alternative Testing Strategy**

1. **Data Processing on Testing Requests and Requirements.** The contractor shall convert data from TSCA Section 4 & 5 regulatory letters and databases and TSCA Sections 4, 5, and 8 hazard and fate databases into a machine readable format (such as ASCII). The contractor shall establish database links for the chemical, guideline, case number, and associated text as pertains to each record.
2. **Data Processing on Existing Chemical Data.** The contractor shall convert data from TSCA Sections 4, 5, 6, and 8 hazard, exposure, and fate databases into a machine readable format (such as ASCII). The contractor shall establish database links for the chemical, guideline, case number, and associated text as pertains to each record.
3. **Data Analysis.** The contractor shall determine which tests are most commonly requested and determine

trends of data requests based on chemical classes and other variables. This knowledge will be used to help optimize future testing strategy (data requests) and to determine tests that would most benefit from alternative testing strategies.

#### Subtask 4. EDSP linear and pathway-based systematic literature reviews

1. **Continuation of EDSP Linear Systematic Literature Reviews.** The Contractor shall continue to support EPA with scientific expertise to perform title/abstract screening, full-text screening, data extraction, and other annotations as directed by EPA on the Fish Short-Term Reproduction Assay (FSTRA), and Male and Female Pubertal Assays initiated under EPW-11-063, Task Order 11; and the Amphibian Metamorphosis Assay and cross-species Fish Short Term Reproduction Assay initiated under EPW-11-063, Task Order 16.
2. **EDSP pathway-based systematic literature reviews.** The Contractor shall assist EPA with developing and implementing approaches for pathway-based systematic literature reviews such as the steroidogenesis and thyroid-related pathways and molecular-initiating events (MIEs). Tasks include articles tagging, title/abstract screening, full-text screening, data extraction, and other annotations as directed by EPA on relevant articles, as well as template design and workflow management.
3. **Data management of EDSP Systematic Reviews.** The Contractor shall support the development and implementation EDSP and OECD Harmonized Templates, reviewer workflows, and reference management in systematic review tools selected by EPA.
4. **Analysis of EDSP Systematic Reviews.** The Contractor shall support the data (including data cleaning), statistical (such as meta-analysis of studies), toxicological, and textual analysis (such as text mining and natural language processing analysis) of EDSP systematic reviews.

#### Subtask 5: Development and Prioritization of the EDSP Universe

The Contractor shall support the curation, clustering, and prioritization of chemical substances from the EDSP Universe of Chemicals including analysis of substance nomenclature, chemical structure, and data on physical-chemical properties, use and exposures, and toxicology.

## II. Deliverables

The contractor shall provide deliverables as shown in Table 1.

Table 1. Deliverables and Schedule

Tasks	Deliverables	Due Dates
Subtask 1	Work plan and task management The contractor shall prepare and submit the work plan in accordance with contract requirements.	

Tasks	Deliverables	Due Dates
Subtask 2	Quality Assurance Project Plan (QAPP) 1. Draft QAPP 2. Final QAPP	1. Draft: 10 days after WA begins 2. Prior to work on environmental data activities
Subtask 3	Development of the EPA Office of Pollution Prevention and Toxics (OPPT) Alternative Testing Strategy	At Work Assignment COR's request.
Subtask 4	EDSP linear and pathway-based systematic literature reviews	At Work Assignment COR's request.
Subtask 5	Development and Prioritization of the EDSP Universe	At Work Assignment COR's request.

- 1. EPA will approve the work plan within 30 days.**
- 2. A Quality Assurance Project Plan (QAPP) is required.** The contractor shall implement a quality system that meets ANSI standard E4-2014 and prepare a QAPP following OPPT/EPA guidelines. No work on the conduct of environmental data operations can begin until EPA approval of the QAPP is obtained.
- 3. This work assignment involves the use of TSCA Confidential Business Information (CBI) for Task 2; otherwise, no CBI is involved.**
- 4. Contractor personnel shall at all times identify themselves as contractor employees, and shall not present themselves as EPA employees. Furthermore, they shall not represent view of the U.S. Government, EPA, or its employees. In addition, the contractor shall not engage in inherently governmental activities, including, but not limited to actual determination of EPA policy and preparation of documents on EPA letterhead other than routine correspondences.**

### III. Period of Performance

This Work Assignment will start with the date of the Contracting Officer's signature and extend through June 12, 2018.

### IV. Estimated Level of Effort: 1,000 professional hours.

### V. EPA Contacts:

#### **Primary Contracting Officer Representative**

Kristan Markey  
WJC East Building, Rm 4106-H, MC 7203  
1200 Penn. Ave, NW, Washington, DC 20460  
Phone: (202) 564-8716  
[markey.kristan@epa.gov](mailto:markey.kristan@epa.gov)

#### **Alternate Contracting Officer Representative**

TBD

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>						Work Assignment Number 1-15				
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:				
Contract Number EP-W-16-017			Contract Period   06/13/2016   To   06/12/2018 Base                      Option Period Number      1			Title of Work Assignment/SF Site Name National Fish Tissue Data Repo				
Contractor BATTELLE MEMORIAL INSTITUTE					Specify Section and paragraph of Contract SOW					
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance  From   06/13/2017   To   06/12/2018				
Comments:										
<div style="display: flex; justify-content: space-between;"> <input type="checkbox"/> Superfund           <span>Accounting and Appropriations Data</span> <input checked="" type="checkbox"/> Non-Superfund         </div>										
Note: To report additional accounting and appropriations data use EPA Form 1900-69A.										
SFO <input type="checkbox"/> (Max 2)										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
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4										
5										
Authorized Work Assignment Ceiling										
Contract Period:                      Cost/Fee:                      LOE: 06/13/2016   To   06/12/2018										
This Action:										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:                      Cost/Fee                      LOE:										
Cumulative Approved:                      Cost/Fee                      LOE:										
Work Assignment Manager Name    Samantha Fontenelle							Branch/Mail Code:			
_____ (Signature)                      (Date)							Phone Number: 202-566-2083			
							FAX Number:			
Project Officer Name    Tyrone Thomas							Branch/Mail Code:			
_____ (Signature)                      (Date)							Phone Number: 202-564-3121			
							FAX Number:			
Other Agency Official Name							Branch/Mail Code:			
_____ (Signature)                      (Date)							Phone Number:			
							FAX Number:			
Contracting Official Name    Jody Gosnell							Branch/Mail Code:			
_____ (Signature)                      (Date)							Phone Number: 202-564-4353			
							FAX Number:			



**PERFORMANCE WORK STATEMENT**  
**EP-W-16-017**  
**Work Assignment 1-15**

**TITLE:** National Fish Tissue Data Repository

**WORK ASSIGNMENT COR (WA-COR):** Samantha Fontenelle  
Standards & Health Protection Division  
US EPA (4305T)  
Washington DC 20460  
202-566-2083  
202-566-0409 FAX

Lisa Larimer (Alternate)  
202-566-1017  
202-566-0409 FAX

**PERIOD OF PERFORMANCE:** Work Assignment issuance through 06/12/2018

**I. Background and Scope of Work**

**Background**

The National Listing of Fish Advisories (NLFA) is a national online database of fish advisories and fish tissue contaminant data collected by states, territories and tribes (hereafter states). It was developed in 1992 and includes advisory information for 50 states, District of Columbia, and the U.S. territories of American Samoa and Guam. It also includes fish tissue contaminant data which served as the basis for state-issued advisories for 48 states. Since 2000, the survey of fish advisories has been performed under an approved ICR for the National Listing of Advisories (OMB Control No. 2040-0226).

In 2010, EPA began a significant modernization of the NLFA. Two new mapping interfaces were designed: one for the general public and the other for technical users. The new application includes easy-to-use drop-down search forms with type-ahead functionality and reports search results in map format, table format, or as a downloadable spreadsheet or PDF report. In 2012, the new application was released publicly. The most recent update of the NLFA occurred in December 2013 and included only the state advisory information for 2011. The NLFA application are available at <https://fishadvisoryonline.epa.gov/FishTissue.aspx> and <https://fishadvisoryonline.epa.gov/Advisories.aspx>.

**Scope of Work**

Under this work assignment, the contractor shall assist EPA with the collection, standardization, and migration of state fish tissue contaminant data.

## **II. Tasks**

### **Task 1 – Work Plan and Quality Assurance Project Plan (QAPP)**

The Contractor shall submit a work plan to the Agency within fifteen (15) calendar days of receipt of the WA. The contractor shall present its technical approach and budget addressing all the tasks in this work assignment.

The Contractor shall develop a Quality Assurance Project Plan (QAPP) to ensure the accuracy and completeness in transcribing and reporting the fish tissue data. The Contractor shall ensure and document that all activities are in accordance with Agency guidance and in compliance with EPA metadata standards. The QAPP shall address the elements in the Modified QAPP Format for Existing Data Projects (Attachment A). The Contractor shall provide all SOPs used for verifying accuracy of data transcription, GIS/georeferencing and other pertinent project-related activities. EPA's guidance on developing QAPPs can be found at [www.epa.gov/quality](http://www.epa.gov/quality).

The QAPP must be approved by the Contractor's quality assurance/quality control (QA/QC) officer and the EPA/OST QA/QC officers prior to the request for data from the states (Task 4). All deliverables shall include a report describing compliance with the QAPP. The work performed in the performance work statement (PWS) shall conform to the Information Quality Guidelines (IQG) Checklist (Attachment B). The completed checklist shall be submitted with the final deliverables.

### **Task 2 - Data Management Plan**

The Contractor shall assist EPA with addressing any deficiencies in a draft Data Management Plan (DMP). The purpose of the plan is to describe the process for collecting, standardizing, migrating and managing the fish tissue data to ensure consistency. The WACOR shall provide the Contractor with the draft DMP (See Attachment C).

In revising the document, the Contractor shall incorporate the following decisions that were made after the draft DMP was completed:

1. **Years of data to be migrated from the NLFA to STORET/WQX/WQX:** 1998 to 2010.
2. **Tissue types to be included:** fillet, whole body, plug, shellfish and wildlife. Currently, the NLFA does not contain shellfish, wildlife and plug data.
3. **Chemical contaminants to migrate:** All chemical contaminants in the NLFA

### **Task 3 – NLFA Data Review and Standardization**

Data quality issues exist with the state fish tissue contaminant data in the NLFA. The Contractor shall assist EPA with the review of state tissue data and perform, as necessary, data cleanup to address data quality and other issues.

The Contractor shall also conduct a thorough review and comparison of the state fish tissue data

in STORET/WQX to the data in the NLFA. The Contractor shall provide the WACOR with a list of states with fish tissue data in STORET/WQX, number of reported results by year, an assessment of the quality of the data, a report of the results of the comparison of the data in STORET/WQX and NLFA.

The contractor shall assist with standardizing chemical analyte name, species taxa, etc.; acquiring missing or additional data parameters (e.g., method detection limits, analytical methods, latitude/longitude, etc.), and addressing other data related issues. The data review and standardization shall be conducted to ensure that data migrated to STORET/WQX is of high quality and can be used for human health risk assessment purposes.

The Contractor shall work closely with EPA and each state to ensure that their data are correctly standardized and QAed before they are migrated to STORET/WQX. For estimating purposes, the Contractor shall assume data from 8 states will be reviewed and standardized.

#### **Task 4 – Data Collection**

For some states, data elements and years of the data may be missing (e.g., lat/long, method detection limits, etc.) or data may be inaccurate because changes were made after the data were submitted to EPA. The Contractor shall support EPA in obtaining missing or accurate fish tissue data from states for 1998 through 2010. This task will require the Contractor work closely with the states.

The Contractor shall also work with the EPA STORET/WQX Team to make any changes necessary to the existing USEPA WQX Web Fish Tissue Template in order for states to provide data not currently included in the template as well as upload their data into STORET/WQX seamlessly using the WQX XML data flow or WQX web tool.

#### **Task 5 – Data Migration**

The Contractor shall add the standardized tissue data into the STORET/WQX and notify each state when its data have been migrated into STORET/WQX. For cost estimating purposes, the Contractor shall assume 50,000 fish tissue sample results shall be added to STORET/WQX.

### **III. Deliverables**

The Contractor shall prepare draft deliverable(s) for review by the EPA WACOR in accordance with the deliverable schedule in section IV or by technical direction (TD). In preparing final written deliverables the Contractor shall incorporate written comments from the EPA WACOR and submit the final deliverables in accordance with the deliverable schedule in section IV or TD. The EPA WACOR will review and approve all final deliverables.

Draft and final deliverables including reports, data, databases and maps shall be provided to the WACOR electronically. Electronic files shall be provided in PDF and/or in the original software (Excel, Word). The Contractor shall use Microsoft Office and Adobe Acrobat software for developing all electronic copies of deliverables associated with the work assignment.

#### **IV. Schedule of Deliverables**

<b>Task</b>	<b>Deliverable</b>	<b>Schedule</b>
1	Work Plan	Per contract requirements
1	Draft QAPP	Within 20 business days of approval of the work assignment
1	Revised QAPP	Within 5 business days of receipt of EPA's comments on the draft QAPP
1	Final QAPP	One month before work assignment completion
1	Information Quality Guidelines	Within 10 business days of completion of the work assignment
2	Revised DMP	Within 20 business days of approval of the work assignment
2	Final DMP	Within 7 business days of receipt of EPA's comments on the revised DMP
3	List of states with fish tissue data in STORET/WQX	As requested by the WACOR
3	Biweekly updates on status of standardization of state data	As requested by the WACOR
4	Status updates on data collection efforts	As requested by the WACOR
4	List of recommended changes to the Fish Tissue Template	As requested by the WACOR
5	Status update on data migration	Within 5 business days of migration of state data

#### **IV. Reporting:**

The Contractor shall include all progress for this WA in the monthly report prepared for this contract. The monthly report shall also include any QA issues encountered and recommendations for resolution. Financial reports shall also be completed as specified in the contract. Financial reports shall also be completed as specified in the contract. The Contractor shall maintain a file of all documentation, including raw data, calculations, assumptions, telephone contacts, and sources of information.

During the period of performance of this work, the contractor shall immediately inform the EPA WACOR by email of any problems that may impede performance along with any corrective actions needed to solve the problem.

#### **V. Contractor Identification:**

Contractor personnel shall clearly identify corporate affiliation at the start of any meeting. While attending EPA-sponsored meetings, conferences, symposia, etc. or while on a Government site, Contractor personnel shall wear a badge which identifies the individual as a contractor employee. Contractor personnel are strictly prohibited from acting as a representative of the Agency at meetings, conferences, symposia, etc.

#### **VI. Travel:**

No travel is anticipated under this work assignment. However, any travel chargeable to this work assignment shall be allowable only in accordance with the limitation of FAR 31.205-43 and FAR 31.205-46, and must be approved by the EPA Project Officer prior to travel taking place.

#### **VII. Printing:**

All copying and printing shall be accomplished within the limitations of the printing clause of the contract.

#### **VIII. Meetings, Conferences, Training Events, Award Ceremonies, and Receptions:**

All appropriate clearances and approvals required by Agency policy in support of any and all conference related activities and expenses, including support of meetings, conferences, training events, award ceremonies and receptions, including the form 5170 for all meetings costing more than \$20,000, shall be obtained by the EPA CL COR as needed and provided to the Contracting Officer Work under conference-related activities and expenses shall not occur until this approval is obtained and provided by the EPA CL COR.

**ATTACHMENT A**  
Modified QAPP Format for Existing Data Projects

## Modified QAPP Format for Existing Data Projects

QAPP Section	QAPP Element
Project Management Aspects	<p><b>A1, Title and Approval (Traditional QAPP Element A1)</b>  <i>Identifies key project officials and documents their approval of the QAPP.</i> Use a short, descriptive title with key words that will help establish the relevance of the project to future searchers. May either use a separate title and approval page or include approval lines on the title page. If using a separate title page, include the project/grant/contract identifier on the title page; if using a single page for both the title and approvals, include the project/grant/contract identifier in the title itself. Include a Revision History page that lists the date, number, and a brief description of each revision.</p>
	<p><b>A2, Table of Contents (Traditional QAPP Element A2)</b>  <i>Helps reviewers and users quickly locate different information within the QAPP.</i> Identify each section and the page number where those sections can be found. List all attachments and appendices. Tables and figures also should be identified in the Table of Contents for long QAPPs (e.g., more than 25 pages). SOPs may be included as attachments or appendices to the QAPP. If SOPs or other data gathering, analysis, or evaluation protocols are not documented in, or attached to the QAPP, they must be readily available to the project team and QAPP reviewers through some other means (e.g., via a website, publicly accessible document, shared network).</p>
	<p><b>A3, Distribution List (Traditional QAPP Element A3)</b>  <i>Names and affiliation of key project personnel responsible for project implementation and/or funding, and who should have the QAPP</i>  Can include placeholders for project roles that have not yet been filled.</p>
	<p><b>A4, Problem Definition &amp; Background (Traditional QAPP Element A5)</b>  <i>Background information and statement of specific problem to be solved, decision to be made, or outcome to be achieved</i>  Describe your project goal and project objectives. Note that identifying a project goal (or "purpose") is different than identifying your project objectives. A project goal provides the answer to the general question "Why am I doing this?" In contrast, project objectives are specific tasks that must be addressed in order to fulfill the project goal.  <u>Example text:</u> Project Goal: Determine if effluent guidelines for X Industrial Category need to be revised. Project Objectives: Identify treatment systems currently in use by the industry, determine if other treatment techniques are available, characterize current pollutant loads from the industry, etc... Note: By clearly defining project objectives, you are laying the ground work for identifying the types of data you need to collect.</p>
	<p><b>A5, Project/ Task Description (Traditional QAPP Element A6)</b>  <i>Summary of work to be performed and products, project schedule, maps, tables, etc., showing locations</i>  This should be a brief description of the project, and should summarize what kind of data you will be gathering, where and how you will obtain this data, your schedule (in terms of significant milestones). In some projects, it may be helpful to include general maps of the area of interest. It is not necessary to include project budgets in the QAPP, although it may be helpful to note if the design was constrained by project budgets and/or schedules. Avoid pasting work plan (deliverables) schedules in this section; instead, summarize major milestones/ overall schedules, but clearly delineating when technical aspects of each phase of the environmental data operations will begin and end. Don't create excessive redundancy by including extensive detail here; details are addressed elsewhere. QAPP length is not important; QAPP substance is.  <u>Example text:</u> EAD and its support contractor will gather existing data from a variety of sources in order to develop technical and economic profiles of the Airport Deicing Industry. Data to be gathered includes information about: airport sizes and types; geographic areas in which deicing operations are performed; deicing processes (e.g., types of operations, chemicals used in deicing fluids, climatic influences on deicing operations); toxicity of deicing fluids or chemicals used in the fluids; waste management strategies (e.g., containment and treatment of deicing fluids); pollution prevention techniques (e.g., recycling deicing fluids, techniques for use of less harmful chemicals or lower volumes of deicing fluids); environmental impacts of airport deicing; pollutant loadings; industry trends in use, containment, and treatment of deicing fluids; and financial information (ownership, management, accounting, potential cost impacts of regulation). The project team will examine a variety of potential sources for such information. Such sources may include: EPA databases (e.g., the Permit Compliance System, Toxic Release Inventory, STORET); other EPA offices that have collected data from this industry or data pertaining to pollutants discharged by this industry; State, local and other federal agencies; and other organizations that may be identified during the course of the data identification and collection process (e.g., federal agencies in other countries that are responsible for air transportation and air transport associations). Data gathering will begin immediately upon approval of this QAPP and continue throughout fiscal year XXXX.</p>

QAPP Section	QAPP Element
	<p><b>A6, Project/ Task Organization (Traditional QAPP Element A4)</b>  <i>Identifies individuals involved with major aspects or phases of the project and their project responsibilities</i>  Include roles and responsibilities of all significant project participants, their contact information, and their respective organizations. (Note “role” is different from “responsibility.” Role refers to a person’s position on the project, whereas responsibility refers to the duties assigned to that role.) Include a project organization chart that visually shows the hierarchy, lines of communication and lines of authority among various groups. It is useful to provide a general chart showing relationships among various organization followed by separate charts that show the details for each organization. No need to include each and every technical staff member who will support the project, but make an effort to include each role (e.g., statistician, data analyst).</p> <p><b>A7, Overall Quality Objectives and Criteria (Traditional QAPP Element A7)</b>  <i>Overall quality objectives for the project and the performance criteria to achieve those objectives</i>  Focus your discussion on the overall quality needed to support the project goals and objectives you described in A5. (Specific criteria used for individual data elements will be addressed in subsequent sections). EPA’s Information Quality Guidelines can be used to help determine the level of quality needed for the intended use of the data.</p> <p><b>A8, Special Training and Certifications (Traditional QAPP Element A8)</b>  <i>Any specialized training or certifications needed by personnel; plans for providing, documenting, and assuring this training</i>  Include specialized skills, training or certification requirements only (e.g., security clearance, CBI training) and plans for ensuring and documenting that these training requirements are met. For existing data projects, identify specialized expertise needed to evaluate the relevance and appropriateness of the existing data to your project needs. (In a primary data gathering study, you have the opportunity to design the study to collect representative samples of interest. To do so, you bring appropriate experts into the design, e.g., engineers, hydrogeologists, fisheries biologists, etc. The same is true for existing data, except that you need their expertise to evaluate the data that was already collected and determine if it meets your needs.) It is generally not necessary include non-specialized training or skills (e.g., chemistry degree, field sampling experience). <u>Example scenario:</u> A project team is interested in studying the health of juvenile fish in the Colorado River. A literature search reveals a study on Colorado River Cutthroats. The paper was published the previous year in a peer reviewed journal, and it indicates that the data were fully validated. The project team considers it to be directly relevant to their needs because it involves a native species in the river, is recent data, relies on validated data, and was peer reviewed. However, the team never consulted a fisheries expert, who would have pointed out that the study targeted fish of harvestable size and weight, which are adults, not juveniles. In this case, the QAPP might state that someone with fisheries expertise is necessary for this project and has been identified (or describes the plan for obtaining this necessary skill set).</p> <p><b>A9, Project-level Documentation and Records (Traditional QAPP Element A9)</b>  <i>Description of process for distributing approved QAPP and other planning documents to staff, a list of final work products that will result from the project (e.g., final report, QA report, Technical Development Document, project database, proposed regulation), a description of the process and individuals for developing, reviewing, approving, and disseminating those work products.</i>  Explain how all project planning documents and records (e.g., the QAPP, SOPs, required forms or checklists) will be managed. This includes how they will be stored and made available to staff. Explain how updates will be implemented and distributed. Identify the final work products that will be produced from the project and explain who will be responsible for developing, reviewing, and approving the products. If they will be disseminated to the public, explain the method that will be used and the processes that will be employed to ensure it is ready for such dissemination. Focus on high-level project planning documents and records and on final work products. Day-to-day recordkeeping and documentation is addressed elsewhere in the QAPP.</p>



QAPP Section	QAPP Element
B. Data Gathering Activities	<p><b>B1, Data Needs (New/Modified QAPP Element)</b>  <i>Detailed description of the existing data needed to fulfill the project goals.</i>  In the Project/Task Description above, you <i>summarized</i> the kind of data you will be gathering. In this section, you will provide a <i>detailed</i> list of the specific data elements that will be needed to support the project goals. Include a description of the scope of the data elements that you need. <u>Example scenario</u>: if you anticipate needing data that reflects a full range of conditions (e.g., multiple treatment options, a wide geographical range), include such details in your discussion. If your project includes the development or update of one or more project databases, identify and define each field in the database(s). The intent of this section is to ensure that all QAPP reviewers, approvers, and users understand exactly what data are needed for the project and to avoid misunderstandings about what a particular data element means. If you have already documented some or all of these fields in another source, such as a database population plan, a data element dictionary, an SOP, etc., it is acceptable to reference that document. However, any documents referenced in the QAPP must be either readily available to all members of the project team and to QAPP reviewers and approvers, or they must be attached to the QAPP.</p>
	<p><b>B2, Potential Data Sources (New/Modified QAPP Element)</b>  <i>Description of the potential data sources that may be used, and the rationale for considering these sources.</i>  Potential sources of previously collected data that should be identified here may include photographs, topographical maps, background information from facility or state files, census data, meteorological data, publications, etc. If a literature search will be conducted, describe the search engines that will be used and the key words that will be searched on. If databases will be used, describe each database in terms of who developed and operates it and the type of data it contains. Define your specific search/query parameters. Similarly, describe any other potential sources of data and the rationale for considering or using them. If you plan to obtain data by contacting individuals or organizations, document these plans. Source selection is often an iterative process with projects that rely on existing data; do not forget to update the QAPP if you need to change your initial source selection strategy. The updated QAPP should describe your original process as well as your revised approach and the reasons for revising the approach.</p>
	<p><b>B3, Criteria for Selecting Data Sources (New/Modified QAPP Element)</b>  <i>Description of the criteria that will be used to evaluate the candidate data sources, and how you define these criteria.</i>  The criteria will vary according to your needs. Examples of possible criteria might include the reliability, applicability, age, and format of the data source, or even the quantity of data available in the candidate data course. Regardless of the criteria that you choose, explain how you define each one. Explain your rating system for each criterion (e.g., a quantitative numeric scale or a qualitative ranking scale). <u>Example</u>: A project team is developing a new database to provide information about potential water system contaminants. The database will include basic identifying information (e.g., chemical name, common name, CAS Registry number, chemical class.), physical characteristics (e.g., molecular weight, density, vapor point, octanol water partition coefficient), usage (e.g., predominant sources, availability, annual production, history of usage), fate/transport characteristics, etc. The database will be entirely populated with existing data from a number of sources, including: published references sources, such as the Merck Index and the CRC Handbook of Chemistry and Physics; databases from EPA, CDC, OSHA, DOE, or other federal agencies; other online databases (e.g., World Health Organization's International Program on Chemical Safety website and database), and the published literature. The team defines the "applicability" of each data source on the following characteristics: the relevance of the information to the intended use of the data in the new database (e.g., a contaminant's properties in a water matrix versus other matrices), and (2) the number of data elements for any given contaminant(s) that can be populated using the source. It then establishes a high, medium, or low ranking system, in which sources that provide five or more directly relevant data elements for a chemical are rated as "high," sources that provide two to four directly relevant data elements for a chemical are rated as "medium," sources that provide only one directly relevant data element are ranked as "low," and sources that provide no directly relevant data elements are rated as "Not Applicable" and, therefore, excluded from further consideration. Similarly, the team decides to define the reliability of the data based on whether the information is current and peer-reviewed, how far removed the data are from the original source, and whether the data are from a preferred and widely used source, and established a similar high/medium/low basis for ranking such data against their reliability criteria.</p>

QAPP Section	QAPP Element
	<p><b>B4, Data Value Selection Approach (New/Modified QAPP Element)</b>  <i>Description of the approach that will be taken to selecting specific data values from the selected data sources.</i>  Once you have screened your potential sources, you may find that more than one source offers the data element(s) you need, that only one source provides values for the data element of interest, that no sources yield the data value of interest, or that some sources address multiple data elements of interest. Describe the criteria and procedures that will be used to determine which value(s) are most appropriate for use in your project. For data that does not meet the pre-established specifications, explain how you will decide if it is usable, and how you will document the decision. <u>Example:</u> For the project described in the B3 element example above, If a data element is available from only one source, and the value is deemed to be reliable, the source is used. If, however, the only available source yields a questionable data value, the contractor will consult with EPA and additional experts, and if it is used, will apply a flag to identify the limitation (e.g., not peer reviewed, documentation of methodology incomplete, conditions not directly comparable to conditions of interest). If a data source provides more than one value for a particular data element, and some are recommended values, some are measured values, and some are estimated values, the contractor will use the recommended value, provided it is scientifically valid. If no recommended value is available, the contractor will use the measured value. The contractor will only use estimated values when no recommended or measured values are available, and the estimated values will be flagged as such in the database. If multiple different values are available for the condition of interest, the contractor will consult the primary literature to determine how each of the conflicting values was generated and to determine which value is most appropriate for use. Preference will be given to values where the explanation is most complete and applicable for the new database.</p>
	<p><b>B5, Resolving Data Gaps (New/Modified QAPP Element)</b>  <i>Description of process for identifying and addressing data gaps that exist after candidate data sources have been evaluated and appropriate data values have been identified.</i>  Projects involving the use of existing data are often cyclical in nature because it is difficult to gather all the data needed in a single step. In most cases, an initial round of data gathering yields important information, but also leaves data gaps that were not located as well as additional data needs that were not previously considered. Describe the process the project team will use to identify data and address those gaps. Also describe the process the team will use to identify new data elements that may be needed. If your processes for addressing data gaps will involve the same data source and data value selection approaches previously described, it is not necessary to repeat those in detail. Instead, refer the reader to the applicable sections and focus describing any new processes, sources, activities, or criteria that will be considered.</p>
	<p><b>B6, Data Gathering Documentation and Records (New/Modified QAPP Element)</b>  <i>Description of processes that will be used to document the sources and data that were identified, considered and either rejected or accepted.</i>  Describe how you will document the source selection results, including any sources that you decided against and the rationale for not using that result. Failure to document your rationale for excluding data sources can lead to accusations of "cherry picking" the data. Where possible, use checklists that capture each of the applicable source/data selection criteria listed above to document your assessment of each candidate source/data element. For data that are deemed acceptable and will be used in the project, explain how you will associate each data element to its original source citation. This includes bibliographic information, telephone contact reports, email messages, etc.  <u>Example text:</u> The contractor will use checklists to document the results of each source and data element assessment. Examples of these checklists are provided in Figures 1 and 2. The contractor will design the project database so that the data source citations and links for each data element can be maintained within each table. The contractor also will design the database so that the entire bibliography, which represents all sources of data in the database, can be viewed and printed as a report by contractor and EPA staff. Data limitations also will be documented directly in the database with the corresponding data value. Any data determined to be of questionable quality will be flagged using standardized data flags (e.g., not peer reviewed, documentation of methodology incomplete). All records will be retained throughout the duration of the contract and for X years after contract closeout. All data sources will be stored with the date the source was accessed, and respective data reports, checklists, and evaluation criteria rankings. The contractor will maintain all data that was obtained in hardcopy format in a physical filing system; an electronic filing system will be used to maintain all original electronically obtained data. Both filing systems will include the complete data source citation, date of access, method of access, and, if applicable, Internet links. Some electronic data may be in the form of a compact disk (CD), in which case, a duplicate copy of the data (CD) will be maintained in the hard copy filing system as well as the electronic filing system.</p>

QAPP Section	QAPP Element
C. Data Management Activities	<p><b>C1, Standardization of Data Elements (New/Modified QAPP Element)</b>  <i>Description of the process that will be used to ensure that units and other key measures are captured and standardized in the database.</i> The units of measurement should be reported for all data sets. If project needs dictate that all be fields be standardized to a single set of units (e.g., U.S dollars for economic data, ug/L for chemical data), identify the standard units that will be required for each data element. If standardization of data elements will not be needed, explain the process for ensuring that the data presented in varying units are comparable enough for use in the project and that project staff members will be able to readily identify differences in units. When considering standard units, consider both (1) simple imperial/metric conversions (e.g., ounces to grams) and (2) whether the units all can really be converted to a common meaning. <u>Example scenario:</u> Some results may be reported in wet weight while others are in dry weight; these are not directly comparable without additional information. How will this be handled? Identify the procedures that will be employed to convert data reported in other units to the standardized units, including any rounding or truncating procedures, and procedures for ensuring these conversions are performed correctly. If you already described your process for ensuring comparability of units in Section B as part of your data selection criteria, you may reference that process rather than repeat it here.</p>
	<p><b>C2, Data Entry (New/Modified QAPP Element)</b>  <i>Description of process for manually entering data obtained from existing sources.</i> Explain the process for manually entering selected data into the project database, who will be responsible for such data entry, and the QC strategies that will be taken to ensure that database accurately and completely captures the original source data. <u>Example text:</u> Two data entry processes will be used for this project. A dual data entry process will be used to capture data elements that are that are presented consistently for a large body of data. For example, this process will be used to capture data obtained from industry survey responses, because the responses are all presented in the same format and are all responding to the same questions. Two clerical staff members will independently enter the designated data from each form into a data entry database created for this purpose. The Database Administrator will then run an automated comparison of the two data sets and generate an error report that identifies any discrepancies. The Data Entry Supervisor will use this report along with the original data set to identify and implement the corrections that are needed. Once the corrections have been made, a printout of the final, corrected database will be provided to the Data Population Manager for review and approval. A copy of the original error report also will be provided so that the Data Population Manager can confirm the corrections made were appropriate. A second data entry approach will be employed for data elements that are not presented consistently, and therefore, require enough subject matter knowledge to identify the data element of interest within the source (e.g., a published journal article that describes treatment technologies). In such cases, the original data entry will be performed by junior members of our technical staff team, and the Data Population Manager will perform a QC review of 10% of the data entered into the database. When performing these QC checks, the Data Population Manager will review the selected data values against their original source to verify that data elements are being populated with the appropriate data and that the data is being transcribed accurately. Regardless of which approach is used, corrective action will be taken to correct all errors identified as well as any systemic problems revealed (e.g., multiple reviewers show an inconsistent understanding of the data value needed for a particular field, one reviewer shows consistent problems in reversing numbers).</p>
	<p><b>C3, Merging or Uploading Electronic Data from Existing Sources (New/Modified QAPP Element)</b>  <i>Description of process for that will be used to merge or upload data from existing electronic sources into the project database and identification of those who will be responsible for doing so.</i> If data are available electronically, and will be merged into the project database, explain the procedures that will be followed to ensure that errors are not introduced during the merging process and that the final database accurately reflects the original dataset(s).</p>
	<p><b>C4, Data Review (New/Modified QAPP Element)</b>  <i>Description of the process for ensuring that the data have been recorded, transmitted, and processed correctly.</i> Examples include checking data entry for transcription, calculation and reduction errors, and checking data transfers to determine if there are any deficiencies, such as missing data elements, registry errors, or shifting of data fields. If you already described your process for such reviews in Sections C2 or C3, it is not necessary to repeat the process here. Instead, you may point the reader to those sections.</p>
	<p><b>C5, Data Storage and Manipulation (New/Modified QAPP Element)</b>  <i>Description of how the existing data will be stored, who will be responsible for access and maintenance, and how it will be incorporated with other project data.</i> This element is used to document the hardware, software, and personnel requirements for managing and incorporating the existing data into the project, and the QC strategies that will be employed to ensure that the integrity of the data is not compromised during data storage, access/retrieval, updates, or other manipulation.</p>

QAPP Section	QAPP Element
D. Data Quality Assessment and Data Analysis Activities	<p><b>D1, Data Quality Verification and Data Quality Reporting (New/Modified QAPP Element)</b>  <i>Description of your process for verifying that the final set of existing data to be used for the project is sufficient to meet your project needs.</i> Describe how you will determine if the overall data meets the criteria originally specified for the project, and how you will document and report these determinations. For data that don't meet the specifications, explain how you will determine if they are usable and how you will document the decision. Note that this differs from Criterion B5, which focused on the completeness of individual data sets gathered from given sources. Section D1 addresses the overall quality of the overall data set you have gathered/assembled. <u>Example scenario:</u> After reviewing all data gathered for the project, you identify some data elements that do not meet the original specifications, but are, the "best available" from the sources identified. In some cases, it may not be feasible (e.g., due to cost or schedule limitations) or possible (e.g., the data just do not exist) to obtain existing data for the data elements in question nor is it possible to collect primary data that would address these gaps. Explain how you document decisions to use such data, and how you will include the description of the data quality limitations in the work product that results from the use of those data (e.g., directly in the project database, in the final project report, in a separate QA report).</p>
	<p><b>D2, Use/Analysis of the Existing Data (New/Modified QAPP Element)</b>  <i>Description of how the data will be summarized or analyzed to meet the project objectives.</i> In the "Problem Definition &amp; Background" you described the "big picture" use of the data. In this section, you will provide details regarding exactly how you will use these data (e.g., calculations, statistics). Explain or list what you will calculate (e.g., mean, median, % removal, a curve of cost vs. flow, etc.) and the data elements that will be used to make those calculations. Include applicable calculations and equations (if known) or explain how you will develop them. If you plan to exclude outliers, explain how you will define outliers and the basis for excluding such data. If exact methodologies that will be used to analyze the data may need to be developed or modified during the course of data analysis, explain the process by which such methodologies will be documented (e.g. via memoranda, analysis plans, email), who is responsible for reviewing/approving their use, and how the methodologies will be checked to ensure they yield the desired products. Describe the activities you will use during the data analysis stage ensure the analyses are being implemented as specified and will support the project objectives. Explain your procedures for identifying and notifying appropriate personnel if changes to the originally planned procedures are warranted, and the process for approving, documenting, and implementing such changes. <u>Example scenario:</u> Explain if and how "not detected" results will be used in calculating average concentrations, explain the specific procedures used to calculate pollutant loads, identify the production parameter(s) that will be used to calculation production normalized loads, describe how percent recycle and percent removals will be calculated, and explain how cost curves will be developed.</p>
	<p><b>D3, Final Verification of Data Analysis and Reconciliation with User Requirements (New/Modified QAPP Element)</b>  <i>Procedures for verifying that the analysis results and work products are usable and support the needs of the project.</i> Describe the process for reviewing the final work product to ensure that the work was generated in accordance with the QAPP, that the work product addresses the overall project goals and objectives (i.e., it provides the information needed to answer the key questions). Describe how you will evaluate whether the analysis results "make sense" in the context of the project. Explain how you will document the results of this assessment, and how you will describe and communicate any limitations of the data or the data analyses that were used to prepare the final work product.</p>

## **ATTACHMENT B**

### Office of Water Information Quality Guidelines Checklist for Non-*Influential Information*

**Office of Water**  
**Information Quality Guidelines Checklist for**  
***Non-Influential Information***

- ☐ The information to be disseminated is covered under The Guidelines.
- ☐ The information is in compliance with EPA's Quality System and other related policies.
- ☐ The information is in compliance with Office of Water's Quality Management Plan.
- ☐ The information is consistent with the OMB definition of "quality," meaning the information has a high level of objectivity, utility, and integrity.
- ☐       Objectivity: information is presented in an accurate, clear, complete, and unbiased manner, and as a matter of substance, is accurate, reliable, and unbiased.
- ☐       Integrity: the information cannot be compromised through corruption or falsification because it is secure from unauthorized access or revision.
- ☐       Utility: the information is useful to the intended users.
- ☐ Meets "transparency" quality standard: the public can understand the source of the information and how conclusions were reached on the information.

\_\_\_\_\_  
Division Director's Signature & Date

\_\_\_\_\_  
IQG Officer for OW Signature & Date

**ATTACHMENT C**  
**DRAFT DATA MANAGEMENT**

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>						Work Assignment Number 1-16				
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:				
Contract Number EP-W-16-017			Contract Period   06/13/2016   To   06/12/2018 Base                      Option Period Number      1			Title of Work Assignment/SF Site Name TSCA Section 8(a) PAIR/CAIR				
Contractor BATTELLE MEMORIAL INSTITUTE					Specify Section and paragraph of Contract SOW					
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance  From   06/13/2017   To   06/12/2018				
Comments: Initiating work assignment on EP-W-16-017. Contractor shall provide work plan within 30 business days.										
<input type="checkbox"/> Superfund                      Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
SFO <input type="checkbox"/> Note: To report additional accounting and appropriations date use EPA Form 1900-69A. (Max 2)										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:                      Cost/Fee:                      LOE: 06/13/2016   To   06/12/2018										
This Action:										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:                      Cost/Fee                      LOE:										
Cumulative Approved:                      Cost/Fee                      LOE:										
Work Assignment Manager Name    Hannah Braun  <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div>							Branch/Mail Code: Phone Number: 202-564-5614 FAX Number:			
Project Officer Name    Tyrone Thomas  <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div>							Branch/Mail Code: Phone Number: 202-564-3121 FAX Number:			
Other Agency Official Name  <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div>							Branch/Mail Code: Phone Number: FAX Number:			
Contracting Official Name    Keith Westry  <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div>							Branch/Mail Code: Phone Number: 202-564-9863 FAX Number:			



## STATEMENT OF WORK

**Work Assignment (WA) Title:** Technical Support for TSCA Section 8(a) PAIR/CAIR and Other TSCA Regulatory Activities

**Contract Number:** EP-W-16-017

**Work Assignment:** #1-16

**Work Assignment Manager (WAM)**

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Washington, DC 20004

## BACKGROUND

The collection of information under Section 8(a) PAIR and CAIR was regulated under the Toxic Substances Control Act (TSCA). The law, enacted in 1976, gives the Environmental Protection Agency (EPA) broad authority to identify and control substances that pose a threat to human health or the environment. Under TSCA Section 8(a), the Agency may require companies to maintain records and submit reports on their chemical manufacturing, importing, and processing activities. The agency has used its Section 8(a) authority to impose recordkeeping and reporting requirements on specific listed chemicals. In implementing its Section 8(a) authority, the Agency issued “model” rules that require submission of detailed production and exposure data on certain listed chemicals.

In an effort to make TSCA regulatory actions more readily available to other government agencies, as well as the public, CCD will utilize information contained in the CCD specific database to create an MS Access Database to populate the ChemView system for generation of ChemView Templates. All information uploaded into the ChemView system would not contain Confidential Business Information (CBI).

The purpose of this work assignment is to provide technical support to EPA for TSCA Section 8(a) PAIR/CAIR information under said rulemaking such as: (1) Prepare and develop a template consistent with the current ChemView format to represent the information captured in TSCA Section (a)

CAIR/PAIR collection (2) collection, review, and formatting of supporting and documents, (3) coordination of chemical identity verification, (4) data entry of information into the approved CCD/ChemView database, and (5) provide technical assistance to EPA WAMs in uploading the resulting MS Access Database files into ChemView. This work assignment will not involve the use of TSCA Confidential Business Information.

Additionally, the work assignment will provide support in document retrieval, collection, indexing and digitization for other TSCA regulating authorities and support completion of requests for information. This portion of the assignment, which may include collections of documents or materials for external requests, will be handled upon request via the WAM in writing.

The contractor will be required to have CBI clearance for this portion of the research and collection of materials, as some materials may be Confidential Business Information (CBI) and thus, should be handled accordingly.

**PERIOD OF PERFORMANCE:** Date of issuance through end of Contract Performance Period.

**LEVEL OF EFFORT (LOE):** The estimated LOE for this Work Assignment is 1000 hours.

**Task 1:           Quality Assurance Project Plan**

This task will involve the preparation of a Quality Assurance Project Plan (QAPP). Under this task the Contractor shall prepare a QAPP to describe the quality assurance practices the Contractor will use to perform the work described in the tasks below.

**Task 2:           Collection of Supporting Documents**

The contractor shall initiate collection of supporting and source documents including Federal Register Notices and TSCA Section 8(a) PAIR/CAIR documents as identified by the WAM in written technical direction. The Contractor shall utilize all available resources, including the Documentum and CIS databases, individual network directories, hard copy files, etc., for collection of the documents. The documents collected in this manner do not contain CBI. In some instances, when the documents are not located in an Agency environment, they may be located on public websites including, but not limited to Regulations.gov, Pubchem, and HeinOnline.

The contractor shall create a pdf copy of all identified documents for which pdf files are not already available. If the documents are not available electronically, the Contractor shall create a scanned image of the document and convert it to a text searchable pdf format. The EPA Work Assignment Manager (WAM) shall provide guidance on naming and storage of the collected documents. The Contractor shall notify the Work Assignment Manager (WAM) of any files which are missing.

**Task 3:           Formatting of Supporting Documents**

The contractor shall provide technical assistance to the WAM in formatting of supporting documents as Adobe pdfs. The WAM shall provide written guidance on the formatting requirements, including suitable metadata requirements for publication in the ChemView system. Formatted pdf documents must be text searchable to accommodate the functionality within the ChemView system. The WAM shall provide written guidance on collection of other TSCA regulatory actions or records whereby the Agency is requesting supporting in research, collection and digital management of said records.

The contractor shall track the progress of completion of these formatted documents and verify that completed reports have been posted to the correct location. For all assigned tasks, the contractor shall notify the WAM of any delays in completion of the reports, and to obtain any items that are not available. As the EPA contact, the WAM is responsible for certifying that all formatted documents are suitable for transmission to the ChemView system, for public dissemination, or for receipt by other EPA staff for review and eventual public dissemination.

**Task 4:           Template Development for TSCA Section 8(a) PAIR/CAIR Information**

The contractor shall provide technical assistance to the WAM in the development and formatting of the template that will be used to consistently format the TSCA Section 8(a) CAIR/PAIR information. The WAM shall provide written guidance and examples of templates of TSCA sections/program information that have been incorporated into ChemView thus far as examples for template development of the TSCA Section 8 (a) information. The contractor shall generator and draft a template accordingly, working with the Technical Contact for guidance. Lastly, they will use samples of extracted data to complete a template draft in order to ensure the template is complete, consistent, and contains all necessary information that pertains to the TSCA Section 8(a) information.

**Task 5:           TSCA Section 8(a) PAIR/CAIR database**

The contractor shall use the collected TSCA Section 8(a) PAIR/CAIR Notices and materials for review and population to the tables within the CCD approved database. All identified chemicals shall be entered into the system using guidance as provided by the WAM. Process will include the completion of a data worksheet, entry of the required data into the appropriate data tables, and QA/QC of the information for quality assurance purposes according to the approved QAPP. Any identified missing or questionable content shall be reported to the WAM. Using the information contained in the database, the contractor shall create MS Access database files for upload into the ChemView system. The ChemView workgroup will review all data and uploaded support documents prior to final approval and publication in the public ChemView database.

5.1       Chemical Identity Verification

The contractor shall review and capture information from the non-CBI documents to populate the chemical identities included in the TSCA Section 8(a) PAIR or CAIR documentation. This identity will include the Non-Confidential Name, as well as any public CAS/Accession Number where available. The WAM shall provide written guidance on what sources and naming conventions shall be used. Due to the vast number of intended users of the system, the chemical identity requirements may vary depending on the intended report. In instances where multiple names are available for a given chemical, the contractor shall provide what information is available, and the EPA WAM will coordinate verification of the suitable names.

5.2       Database Data Entry

The contractor shall use the non-confidential documents collected, and guidance provided by the WAM to enter data into the CCD approved database. The written guidance shall detail the specific fields, formatting requirements, and examples of where the information can be found for each data field. The contractor shall pose any questions to the WAM as soon as possible to allow additional guidance to be provided.

In addition, the database contains a “Comment” field designed for the contractor to enter any comments, observations, or notes they wish the WAM to review. This will allow for a formal accounting of what information was exchanged and allow for future improvements to guidance documents and/or enhancements to the database. All edits to the database shall be at the direction of the WAM.

### 5.3 Report Generation

The contractor shall assist the EPA WAM in creation of various reports using the export functions of the CCD approved database. The contractor shall coordinate with the WAM the procedures for generation of the reports and any formatting requirements that may be needed.

## **Task 6: Research and Collection of TSCA Regulatory Activities and Information**

The contractor shall provide support to EPA staff in the documents and materials retrieval, collection, indexing and digitization for other TSCA regulating authorities and support completion of requests for information. All requests for support and research collection will be made directly to the WAM. The contractor will be provided with a reasonable timeline for completion of collection of materials. All identified material shall be entered into an index log system on an MS Access system, maintained by the contractor, but kept by the Agency/WAM. In addition, the database contains a “Comment” field designed for the contractor to enter any comments, observations, or notes they wish the WAM to review. This will allow for a formal accounting of what information was exchanged and allow for future improvements to guidance documents and/or enhancements to the database. All edits to the database shall be at the direction of the WAM.

The contractor should use all available sources for the collection of the documents including the Documentum and CIS databases (e.g., electronic version of the files from the Confidential Business Information Center--CBIC, PMN Gold Workflow System, the CBI Local Area Network (LAN), individual network directories, hard copy files, etc.). The contractor will go to each of the known sources to find documents relating to each inquiry or substance case request to identify the correct document. Documents corresponding to related requests, chemical inquiries, etc. will be utilized for information gathering purposes for the purposes of this work assignment. Should the documents collected contain CBI information, the contractor will begin the initial sanitization of the documents and provide them to the WAM after completion of the sanitization process. The contractor shall provide support to completely and accurately remove CBI from documents. The WAM and/or EPA staff will review for CBI content before returning to contractor or revision or completion of sanitization activity.

When the documents are not located in a CBI environment, they may be located on public websites such as Regulations.gov, Pubchem, and HeinOnline. Subscription or licensing fees may apply to obtain copyright documents that are not in the public domain.

Said task further includes making copies of documents and/or digitizing the paper collection. Process will include the completion of a data log sheet, entry of the required data into the appropriate data tables, and QA/QC of the information for quality assurance purposes according to the approved QAPP. Any identified missing or questionable content shall be reported to the WAM.

The WAM and supporting CCD staff will review all data and content of supporting documents prior to final approval and release for public dissemination, including use by other Federal or non-Federal entities. The task is completed on as needed support role by the Contractor via the WAM.

#### **Section A SPECIAL TRAINING REQUIREMENTS/CERTIFICATION**

All staff supporting this Work Assignment will possess all necessary education requirements and credentials before performing work. All project personnel will have a working knowledge of TSCA. Any staff not specifically listed above will be fully trained prior to performing any work on this project.

All contract staff handling CBI under this Work Assignment are certified to do so under the contractor's and EPA's existing, approved TSCA CBI Security Plan. This Security Plan specifies that before contractor staff members are permitted to have access to CBI, they are required to have completed CBI Security Training. Once staff members have successfully tested on the information covered in this training, they receive CBI Security certification and are placed on the contract's Access Control List of the contracting staff authorized to access CBI under this Work Assignment. Staff on this list renew their training certification annually.

**DELIVERABLES:** All deliverables shall be submitted to the WAM electronically (Adobe pdf).

- Task 1**            The Contractor shall submit a QAPP within 2 weeks of approval of the work plan.
- Task 2**            The contractor shall submit to the EPA WAM written updates on the status of completion of the tasks on a monthly basis. The update should include identification of any missing documents.
- Task 3**            The contractor shall submit to the WAM written updates on the completion of the subtasks in this task on a monthly basis. The update should include reporting of progress of documents formatted, notification of any quality issues or concerns for these documents, and reporting of documents ready for WAM review.
- Task 4**            The contractor shall submit to the WAM written updates on completion of the subtasks in this task on a monthly basis. The update should include reporting on the progress of template development, chemical identity verification, including notation of changes in identities and any updates made to the CCD approved database. The contractor shall report progress on the completion of the data entry.

#### **ADDITIONAL INFORMATION**

- Contractor personnel shall at all times identify themselves as contractor employees, and shall not present themselves as EPA employees. Furthermore, they shall not represent views of the U.S. Government, EPA, or its employees. In addition, the contractor shall not engage in inherently governmental activities, including but not limited to actual determination of EPA policy and preparation of documents on EPA letterhead other than routine correspondences.
- In an effort to maintain standards during review and completion of all tasks, an audit of data quality may be performed upon request to assess the accuracy and completeness of factual data processing, data entry, or CBI sanitization to ensure submitted work products are of high quality and meet the quality standards for this Work Assignment